EXHIBIT DX1

TO DECLARATION OF MONICA L. DAVIES IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF MICHAEL KEEN, P.ENG., MBA

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

SM/lms

In re: Bair Hugger Forced Air Warming Products Liability Litigation — MDL No. 2666 (JNE/FLN)

- - - - - - - - - - -

This is the Deposition of MICHAEL KEEN in the above-noted matter, taken at the offices of VICTORY VERBATIM REPORTING SERVICES, Suite 900, Ernst & Young Tower, 222 Bay Street, Toronto, Ontario, on the 14th day of July, 2017.

- - - - - - - - - - - - - - - -

A P P E A R A N C E S:

GENEVIEVE M. ZIMMERMAN -- for the Plaintiffs
Meshbesher & Spence, Ltd.
1616 Park Avenue South
Minneapolis, MN 55404

PETER J. GOSS -- for 3M Company and
VINITA BANTHIA Arizant Inc.
Blackwell Burke P.A.
431 South Seventh Street
Suite 2500
Minneapolis, MN 55415

ALSO PRESENT:
Gabriel Assaad
Kate A. Crawford

INDEX OF PROCEEDINGS

	PAGE NUMBER
MICHAEL KEEN, sworn	
Examination by:	
Ms. Zimmerman	3 - 338
Re-Examination by:	
Mr. Goss	338
Index of Exhibits	339
Certification	340
Errata Sheet	341

--- upon convening at 10:00 a.m.
--- upon commencing at 10:01 a.m.

MICHAEL KEEN, sworn
EXAMINATION BY MS. ZIMMERMAN:

Q. Good morning, Mr. Keen. My name is Genevieve Zimmerman, and we just had an opportunity to meet a few minutes ago. I am one of the attorneys that represents a little over 2,600 people in the United States that have filed lawsuits against 3M and Arizant related to the Bair Hugger product, and I am here to ask you some questions about the expert report that you provided in this matter.

As we go forward today, I am going to be asking you some questions and the court reporter will be taking down some...taking down both my questions and your answers. So if we can do our best to make sure to let the other complete the question or complete the answer, that will make the court reporter's job easier. Is that fair?

A. Yes.

Q. All right. And you seem to be doing a good job to begin with, but one thing we do, just in normal speaking with one another, is do incomplete verbal answers like m'hmms and uh-huhs. That doesn't

come out real clear on the transcript, so if you can, try to make sure to give an affirmative yes or no, and if additional explanation is necessary, we can go through that as well. Is that fair?

A. Yes.

Q. All right. Now, if I ask you a question that you don't understand in some way, will you please let me know that you don't understand it?

A. Okay.

Q. All right. And if you answer a question that I ask, I am going to assume that you understood the question I was asking; is that fair?

A. Yes.

Q. Okay. Now, have you had your deposition taken before?

A. In relation to this case?

Q. Ever.

A. I have had a deposition before, yes.

Q. All right. When?

A. I don't remember the exact time, a number of years ago. I had a couple of different cases where I had depositions done.

Q. How many times?

A. I would think maybe about five or six, potentially.

Q. All right. And were those in connection with lawsuits pending in Canada?

A. Yes.

Q. All right. Have you been deposed before for any lawsuits pending before American courts?

A. No.

Q. All right. And for whom did you provide testimony in these Canadian cases?

A. In every one of these cases, I was representing my employer, St. Michael's Hospital.

Q. All right. What was the nature of the lawsuit?

A. Two of them were in regards to lawsuits that related to construction redevelopment that was happening at the hospital, and the remaining had to do with labour cases with staff members and the unions.

Q. Did any of these cases involve issues touching on infection?

A. No.

Q. Did any of these cases touch on issues involving an HVAC system?

A. Yes.

Q. All right. Tell me about that.

A. One of the cases in one of the construction...sorry, two of the cases, actually. So one of the cases was the hospital in defence of claims against a mechanical contractor. So, obviously, by nature of their work, they were working on HVAC systems in the construction of the hospital. And so, as part of their claim or their work, that relates to HVAC systems.

The other one was also, again, from a construction standpoint, whereby a neighbouring property to...a construction site that the hospital was working on had some HVAC issues that were part of the case.

Q. Did any of these claims involve injuries?

A. No.

Q. Okay. And you understand that you have been designated by 3M Company and Arizant as a potential expert witness in the MDL, or multi-district litigation, that is currently pending in United States District Court, correct?

A. Yes. They have asked me to provide opinions, as contained in my report, on topics related within my report here on those issues, yes.

Q. Okay. And we will get to your report

throughout much of today, I think. One additional matter of housekeeping, as I ask you questions, I would ask that you don't guess as you provide an answer; is that fair?

A. Yes.

Q. Okay. What did you do to prepare for your deposition today?

A. I read through my report again and the reference documents that were in the report. We had a preparatory meeting yesterday with Pete and Vinita from Blackwell Burke in preparation for today's deposition as well. And I did a few Google searches on some terms as well of items within the documents as well.

Q. All right. What search terms did you use for your Google searches?

A. The majority of them had to do with a definition of a term I needed to remind myself of the exact meaning of.

Q. Do you know which terms you needed to be reminded about?

A. I don't recall all of them. A couple of examples might include asepsis. I am trying to think of some of the others right now. I can't recall right now, but...at this moment, sorry.

Q. Okay. And, as I take your deposition today, you understand that the plaintiffs that have filed lawsuits in the American court system have a right to understand the full scope of the opinions you intend to offer in this matter; is that right?

A. I don't have a full understanding of sort of the system or the legal proceedings.

Q. Fair enough. You're not a lawyer, I assume?

A. No, I am not a lawyer, no.

Q. Okay. And this is the first time that you have been involved in a case pending in the American court system; is that right?

A. That is correct.

MS. ZIMMERMAN: Okay. I am going to provide to you a document that I think we will mark as Keen Exhibit 1.

--- EXHIBIT NO. 1: United States District Court subpoena to Michael Keen, c/o Blackwell Burke, dated June 7, 2017

BY MS. ZIMMERMAN:

Q. Have you seen this document before?

A. Yes.

Q. All right. And, specifically, I will direct you to pages 4 and 5 of this document, which is "Documents to be produced". Do you see that?

A. Yes, I do.

Q. Did you understand that this subpoena called for documents for you to be producing to the plaintiffs in this litigation?

MR. GOSS: Object to form.

THE DEPONENT: Yes.

BY MS. ZIMMERMAN:

Q. All right. And I assume that this subpoena was produced to you by Mr. Goss or one of the attorneys for 3M?

A. I can't remember exactly how it was forwarded to be, but, yes, I received it.

Q. And did you go through your files to determine whether you had documents that were, in fact, responsive to this subpoena?

A. Yes, I did.

Q. All right. And did you produce any documents to counsel for 3M that are responsive to this subpoena?

A. Yes, I did.

Q. What are those documents?

A. I produced...I had...I had document papers that I had highlighted and I produced those to counsel.
Q. And are those in the folder that you brought with you today?
A. I believe one or two of them might be, but the majority are not.
Q. All right. So I am going to go one-by-one through the documents that are requested here. So the first request is for:
"...All documents reviewed by the deponent in anticipation of or in preparation for this deposition..."
Do you believe...or did you find documents responsive to that request?
A. Yes.
Q. Approximately what documents did you identify that are responsive to that request?
A. The majority of those documents are contained as references within my report.
Q. All right. Are there any documents that are responsive to this request that are not references to your report?
A. Yes. I have a few...a couple of other papers provided to me by counsel that were not

used as references in the report.
Q. And Mr. Goss identified at the beginning or prior to the start of this deposition that there was at least one additional paper, I think, you were provided yesterday. Is it Bernard?
A. Yes, that is correct.
Q. All right. Is that the only other paper that was provided to you?
A. Yesterday?
Q. Yes.
A. Yes.
Q. All right. Were there any other articles or other papers produced by counsel for 3M before yesterday that are not references in your report?
MR. GOSS: And I want to clarify too, in your question, are you including documents that he would have reviewed since the subpoena was served or since he responded to the subpoena; in other words, up to yesterday?
MS. ZIMMERMAN: Right. Yes. I guess we would like to know both and we can separate it into time periods...
MR. GOSS: Okay.

MS. ZIMMERMAN: ...if that would be easier.

BY MS. ZIMMERMAN:
Q. First, I would like to know about any and all documents that you had that would have been responsive to the subpoena, which I think was issued at the beginning of June and it would have been due on June 21st. Next, I would also like to know about any documents that you reviewed in preparation for today.
A. Sure. So I have answered as far as the documents prior to the subpoena.
Q. Okay.
A. Post the subpoena, I have been provided with a number of deposition documents to review and the Bernard document, and I believe that is all, to the best of my memory.
Q. All right. What depositions have you been provided?
A. I have been provided with Kuehn, not to be confused with myself.
Q. It is a little confusing.
A. Yes.
Q. The Canadian...

A. K-U-E-H-N, I believe, is the spelling.
Q. Yes.
A. I have been provided with Koenigshofer, Elghobashi. There is another one that is not coming to the tip of my tongue right now.
Q. Mike Buck?
A. I believe that's it.
Q. Did you receive a copy of Jim Ho's deposition?
A. Yes, sorry. Yes, I also have Jim Ho's.
Q. Any other depositions that you were provided?
A. Not that I can remember right now, no.
Q. When were you provided these depositions?
A. I was provided these over the course of the past two weeks, I believe.
Q. And certainly with respect to the Minnesota Kuehn, it had to have been sometime since Monday, as his deposition was taken then. Were you provided the deposition of any of 3M's employees, for example?

Page 14

A. No, I wasn't.
Q. Were you provided the deposition of any other fact witnesses in this case?
A. There was one other deposition I received. It was Crowder.
Q. Crowder, yes. So, just to recap, it seems that you have received depositions of Kuehn, Koenigshofer, Said Elghobashi, Mike Buck, Jim Ho, and Crowder. Are there any other depositions that you have been provided?
A. No, I don't believe so.
Q. All right. Have you been provided any 3M documents?
A. Yes, I have.
Q. What 3M's documents have you been provided?
A. At this time, I can't remember exactly which documents.
Q. Do you know when you were provided the 3M documents?
A. Any of the 3M documents would have been prior to my subpoena and over the past...the course of the past five months, I believe.
Q. All right. Have you read any of the depositions that you were provided?

Page 15

A. Yes, I have.
Q. Have you read all of them?
A. No, I haven't.
Q. Which ones have you not read?
A. I have not read Elghobashi and I have not read Buck.
Q. And that leaves, I think, Kuehn, Koenigshofer, Jim Ho, and Crowder; is that right?
A. That is correct.
Q. Okay. And any 3M documents that you were provided with, you received prior to this subpoena; is that fair?
A. Yes.
Q. Okay. What is the volume of documents that you have been provided by 3M, number of pages? And I have asked you not to guess, but I would...in this instance, I would ask for your best estimation.
A. It's tough to guess. I don't know if I would be able to accurately estimate that. The best estimate would be the list of references I have in my paper...
Q. All right.
A. ...as far as referenced documents. And then you have seen the list of depositions.

Page 16

Q. Yes.
A. And so, I wouldn't be able to guess the total number of pages, but that list plus a few other documents on top of that would be the total sum of the documents.
Q. Okay. So, as a general matter, the list of references in your report is most of the documents you have been provided; is that fair?
A. That is fair.
Q. Okay.
A. Sorry, in addition to the depositions, obviously.
Q. Right.
A. They are big page documents.
Q. Yes, they are very thick.
A. So, by page volume, they are probably...make up a lot of the proportion.
Q. That is right. And have you...you did at least some Google searching, it seems. Have you done any other independent research in connection with your work on this matter?
A. Not beyond the Google searching, no.
Q. All right. So, essentially, all of the materials or references that you have are documents that you have received from 3M; is that

Page 17

fair?
MR. GOSS: Object to form.
THE DEPONENT: Those documents would be those received from counsel or ones that I found through my Google search.

BY MS. ZIMMERMAN:
Q. Okay. And that is kind of part of what I am trying to narrow in on. What have you done...independent of what documents you may have received from lawyers for 3M, what have you done to educate yourself about the opinions you render in here?
A. Sorry, I may be misunderstanding. I thought I answered that the Google search that...
Q. Okay.
A. I am not sure what the...maybe you could...
Q. And was it...
A. ...restate your question somehow?
Q. Sure. No, I appreciate you stopping me. Was it just a Google search this week? And I think you've mentioned trying to familiarize yourself with terms that you may not understand, like asepsis. Were there any other Google searches that you did?

Page 18

A. I did other Google searches throughout the course of my review of this case. Through any review of documents that I did, I was frequently using a Google search, so...
Q. Okay. Did you do any searches on, for example, PubMed?
A. Not that I recall.
Q. Do you use PubMed much?
A. Not really, no.
Q. Okay. Do you have any online medical or engineering research tools that you would have access to?
A. I have online references for the standards, organizations, communities that I belong to, but no other sort of research subscriptions.
Q. Okay. Getting back to the subpoena that was provided to you by counsel, you reviewed the requests here and they are numbered 1 through 18. Turning to number 2, the subpoena requests:
"...All correspondence and documents between the deponent and non-lawyers, including but not limited to notes, investigations, test results, raw data, experiments, demonstrations, photographs, videos, movies, or any other items gathered, tested or

Page 19

created in the course of the deponent's investigation of this case..."
Did you identify any documents or other items that would be responsive to request number 2?
A. Yes, I did.
Q. And what did you identify?
A. I identified some correspondence that was not with the lawyers.
Q. And who was it with?
A. I had three different correspondences that I provided.
Q. Okay.
A. The first was with the director of perioperative services at the hospital, at St. Michael's Hospital.
Q. And who was that?
A. That is Catherine Hogan.
Q. And what was the second?
A. The second was with my father.
Q. All right. And who is your father?
A. Robert Keen.
Q. And what was that communication regarding?
A. That communication was sharing a draft of my report and asking his opinion as to

Page 20

format and writing style.
Q. And what was the third?
A. The third was a LinkedIn correspondence with Dan Koenigshofer.
Q. All right. And each of these was provided to counsel for 3M?
A. Yes.
Q. Turning to number 3:
"...Copies of all of [your] notes, whether hand-written or typed, related to expert work in this matter..."
Did you identify documents responsive to that request?
A. No. I did not have any independent notes.
Q. All right. Why not?
A. The majority of the reason would be because I didn't take any independent notes, and I either was highlighting documents, for the most part, and typing directly into my draft...draft report.
Q. All right. And the report is something that you personally typed?
A. Yes.
Q. And then, turning to number 4, that is:

Page 21

"...Copies of all documents provided to the deponent [you] by Defendants' counsel, on which the deponent has made notations, highlighting, or underlining..."
Did you identify any documents responsive to that request?
A. Yes, I did. I provided several documents that I had highlighted.
Q. And you provided those to counsel for 3M?
A. Yes, I did.
Q. All right. Were those principally articles?
A. They were principally articles that are contained within the references of my report.
Q. Were there some documents that are not included as references to your report?
A. I think...I think I highlighted Dan Koenigshofer's report, and I may have provided that as well.
Q. Okay. But anything that you found that was responsive to number 4 you provided to counsel for 3M?
A. Yes, I did.
Q. All right. Request number 5 is a

Page 22

copy of all items that you may use as demonstrations, exhibits or aids in the course of testimony at the trial of this matter. Have you prepared any such documents at this time?

A. No, I did not.

Q. Okay. Request number 6 asks for:

"...A list of all books, treatises and articles authored or co-authored by the deponent..."

Are there any documents that are responsive to this request?

A. No.

Q. Have you written any books, treatises or articles?

A. I have not directly authored a published book for publication, but I have been a writing member of many standards, of which I was on a committee for writing that standard.

Q. But nothing that you have personally authored or co-authored that is listed in your name; is that fair?

A. That is correct.

Q. All right. No peer-reviewed articles that you have written?

A. No.

Page 23

Q. Okay. Number 7 asks for:

"...A list of all books, treatises, articles, publications, or materials which the deponent [you] considers authoritative with regard to the opinions [you have offered] in this case..."

Have you identified any documents that would be responsive to request number 7?

A. I believe anything that would fall in this category is included as a reference in my report.

Q. All right. So the references in your report are a complete list of the documents that you would find authoritative in this matter?

MR. GOSS: Object to form.

THE DEPONENT: I believe the list of my references are the ones that I have used as a reference for this report. I believe that there are others that may be authoritative or might apply but were not referenced in...directly in my report.

BY MS. ZIMMERMAN:

Q. All right. And, at this time, have you identified any of those authoritative texts or

Page 24

publications and provided such a list to counsel?

A. I have not provided any other list of authoritative publications, other than what is included in my reference list.

MS. ZIMMERMAN: Okay. Number 8 asks for:

"...A copy of [your] resume and/or curriculum vitae..."

And I will mark, I guess as Exhibit 2, what was attached as Exhibit A to your report.

--- EXHIBIT NO. 2: Curriculum vitae of Michael Keen

BY MS. ZIMMERMAN:

Q. Is this a current copy of your resume at this time?

A. Yes. This is the copy I provided with my report.

Q. And this continues to be accurate?

A. I believe so.

Q. All right. Number 9 in the subpoena asks for a copy of:

"...The deponent's engagement agreement concerning services rendered in connection with this matter..."

Do you have an engagement agreement with counsel for

Page 25

3M?

A. I apologize, I was finishing reading a couple of things. Can I ask you to restate the question?

Q. Sure. Question number 9 on the subpoena that we are going over asks for a copy of:

"...The deponent's engagement agreement concerning services rendered in connection with this matter..."

Do you have an engagement agreement with 3M or counsel for 3M?

A. I have e-mail correspondence relating to my engagement on this...on this case.

Q. All right. And did you provide a copy of that to counsel for 3M?

A. I don't know if I did, actually.

Q. Or you would perhaps assume that they had a copy of that?

A. Yes. That original e-mail trail started with BLG, with Tim Buckley and Kate Crawford. So Blackwell Burke might have been copied on the original correspondence, but all of that will be in the correspondence with either of the two of BLG or Blackwell Burke.

Q. And BLG, you mentioned Tim Buckley

Page 26

and Kate Crawford. Kate Crawford is here today?
A. Kate Crawford is here, yes.
Q. All right. And were they the first people to retain you in connection with the Bair Hugger matter?
A. Yes, they were.
Q. And when did that take place?
A. I believe the first contact was either December 2016 or January of 2017.
Q. All right.
A. And the retainer would have happened sometime later, shortly thereafter.
Q. And you were provided a financial retainer for your services as well, or a written retainer reflecting your agreement?
A. The e-mail correspondence that we had reflected a rate that I would be paid for my work.
Q. All right. And that, I think, starts to go into request number 10 on the subpoena, which requires or requests:
"...An itemized list of time, charges, and expenses for services or opinions rendered in this case, including an itemization for said services performed by any persons employed by the deponent in this case..."

Page 27

Have you identified any documents responsive to request number 10?
A. I have submitted three invoices to counsel on this matter.
Q. And when were those invoices submitted?
A. One would have been early in 2017. I can't remember the exact date. And I believe one was on April 30th, the second one. I believe the third one might have been June 2nd. Those are approximate.
Q. All right. What is the hourly rate that you charge in this matter?
A. The hourly rate started as $290 per hour Canadian, and we have adjusted that for a U.S. payment of $250 an hour U.S. to reflect the exchanges.
Q. All right. And these invoices have all been provided to counsel for 3M, is that fair?
A. Yes, they have all been provided to counsel for 3M.
Q. And you have been, in fact, paid for the time that you have spent researching and providing your consulting work in this matter so far?
A. I have received payment on the first

Page 28

of those three invoices.
Q. But not the second two?
A. Not the second two yet.
Q. Okay. All right. With respect to document number 11...pardon me, request number 11, it asks for:
"...All documents or other materials [that] the deponent intends to show the jury in this case..."
Have you prepared any such materials at this time?
A. I have not prepared any other materials, other than my report.
Q. Request number 12 asks for:
"...The deponent's correspondence file (excluding correspondence with [the] Defendants' counsel) in connection with this case..."
Do you have any documents responsive to request number 12?
A. If I understand number 12 correctly, I believe I answered that in respect to number 2, and the three correspondence I had that were not with legal counsel.
Q. Fantastic. Request number 13 asks for:

Page 29

"...other documents, photographs, or other material not specifically listed above on which the deponent relies for his opinion(s)..."
Are there any documents or other items that you have not specifically listed above upon which you rely for offering your opinions in this matter?
A. No. I believe I have mentioned all other documents at this stage.
Q. Have you been provided copies of reports of other experts retained by 3M in this matter?
A. Yes, I have.
Q. Okay. What have you been provided?
A. It's going to be tough for me to provide you a whole list, but some of the papers that I have received have been experts retained by 3M.
Q. And I will represent to you that I see, as one of the citations in your report, a reference to Settles.
A. Yes, Settles would be one of those.
Q. And that is listed, I think, as letter (w) in your references; is that correct?
A. Yes, that is correct.
Q. I don't see a notation or a reference

Page 30

to any other defence expert report. Have you been provided other defence expert reports?

A. To be honest, I can't recall if there are any others that were defence experts for the counsel, other than sort of what I have listed as what I have been provided. I don't always know which...whether they are defence counsel experts or not, so...

Q. Okay. In any event, if you had been provided additional reports and you have relied upon them in offering your opinions, they would be referenced in your report; is that fair?

A. Yes. I have a few documents, as I mentioned, that were...I have a few documents, as I mentioned, that I have reviewed as part of this. But if I did not rely on the information, I did reference it.

Q. Okay. And, conversely, everything you did rely on is referenced in the report; is that fair?

A. Yes, I believe so.

Q. And I take it from your answers outlining the three correspondence, responsive both to number 2 and number 12, that your answer to number 14 may be the same. There the subpoena asks for:

Page 31

"...All written communications (including e-mails) between the deponent and any other expert (retained or consulting) of the Defendant..."

Are there any other documents that are responsive to request number 14?

A. There are no other e-mail communications, other than the ones I already mentioned.

Q. Have you ever met with any of the other experts in this matter?

A. Yes, I have.

Q. Who have you met with?

A. I have met with Dan Koenigshofer. I have met with Farhad Memarzadeh. I have met Russell Olmsted. I believe that is all.

Q. All right. And have you met with any of these three gentlemen, Dan Koenigshofer, Farhad Memarzadeh...

A. Memarzadeh.

Q. Memarzadeh?

A. Memarzadeh.

Q. Or Russell Olmsted with respect to the Bair Hugger matter?

A. Olmsted, Memarzadeh, I have not

Page 32

spoken with about the Bair Hugger matter. Dan Koenigshofer and I have discussed the Bair Hugger matter in non-relevant terms, such as, "Hey, we're both working on this case. It's a lot of work," that kind of thing, but nothing substantial to the technical aspects of the case.

Q. All right. And when did you discuss the matter with Dan Koenigshofer?

A. There is the original LinkedIn correspondence I mentioned, and then the two of us met in person at a committee meeting at the end of June.

Q. All right. And do you know if that was before or after he was deposed in this matter?

A. That was after he was deposed.

Q. And what did he talk about?

A. He talked about the bright lights and the cameras and difficult questioning. Again, very general terms, not specific or substantive.

Q. All right. Turning to request number 15 on the subpoena, here we request:

"...All communications (including but not limited to e-mails) between the deponent and Defendants, including any agent of [the] Defendants..."

Page 33

Do you have any documents that are responsive to number 15?

A. No, I do not.

Q. With respect to number 16, the subpoena requests:

"...Any study, test, trial, experiment, research and/or data analysis the deponent sponsored, conducted, performed, proposed, attempted, considered, discussed, planned, arranged and/or performed on the Bair Hugger warming system or filter for use with any Bair Hugger warming system, including any work in process..."

Have you identified any documents or information responsive to number 16?

A. No, I haven't, and there wouldn't be any, other than as part of my work on the ASHRAE committee. We sponsor research projects in various HVAC topics related to healthcare. And I have been involved in these committees, the decisions to sponsor certain projects. Any and all of these decisions were independent of this case.

Q. Are there any projects that you are currently involved in, projects, tests, experiments, that sort of thing, that you're involved in with

Page 34

connection...or in connection with your work with ASHRAE that specifically touch on Bair Hugger?
A. There is one research project that the committee has been looking at with respect to power consumption of various pieces of equipment in a healthcare facility. I do not know if the Bair Hugger is included in such a study. I am not fully aware of the full list. That is a possibility. But that would be the only thing that I can think of that would have a potential...
Q. And is it fair to say that, as you were retained to provide opinions in this matter, you have not been asked to do any experiments on the Bair Hugger; is that fair?
A. That is correct, other than I have actually, you know, touched a Bair Hugger, turned it on, looked at it. I haven't performed any formal experiments.
Q. Okay. And we will get to that. Would you consider your work, with respect to consulting, essentially complete at this time, other than having your deposition taken today?
A. For this case here?
Q. Yes.
A. Yes. I believe that, barring any new

Page 35

information or new requests from counsel, that I have completed what they have originally asked me to do.
Q. Okay. And do you understand the general causation discovery has been closed in this case?
A. I am actually not aware of the whole legal proceeding.
Q. Okay. Turning to document number 17...or request number 17 on the subpoena, the request is for:
"...All documents sent to or received from any forced air warming system manufacturer about the alleged actual or potential hazards and/or safety risks of forced air warming and/or the Bair Hugger warming system..."
Do you have any documents that are responsive to request number 17?
A. Other than documents from 3M that we spoke about earlier that may have been provided to me by counsel, I have not had any direct communication to or from any forced air warming system manufacturer.
Q. All right. So you're not in communication with, for example, Stryker, who

Page 36

manufactures the Mistral system?
A. I actually wasn't aware that Stryker produced a Mistral system.
Q. Mistral.
A. But Stryker is a vendor that the hospital deals with, so...
Q. Stryker makes a lot of different things in the hospital, right?
A. They do.
Q. Okay. Hospital beds, for example, and all manner of things?
A. Yes.
Q. All right. And up until I just asked this question, you weren't aware that Stryker distributes a forced air warming product?
A. No, I was not.
Q. Okay. And then the last request on the subpoena is for:
"...All compilations of electronic data and computer files created by the deponent, including but not limited to pictures, videos, animation, CFD files, etc..."
Have you identified anything that would be responsive to request number 18?
A. The only thing I have created that

Page 37

would respond to this would be contained within my report.
Q. Okay. The report is the sum total of what you have produced in this matter; is that fair?
A. Yes.
MS. ZIMMERMAN: All right. And we may come back to parts of this. I will hand you two additional documents. This will be Exhibit 3.

--- EXHIBIT NO. 3: E-mails between Michael Keen and Catherine Hogan, dated April 21, 2017

BY MS. ZIMMERMAN:
Q. Do you recognize this document?
A. Yes.
Q. And is this one of the three pieces of correspondence that you referenced as we were walking through the subpoena?
A. Yes, it is. This is the correspondence of Catherine Hogan, perioperative director from St. Michael's Hospital.
Q. All right. And you are inquiring of Ms. Hogan whether or not your hospital uses warming techniques for patients in orthopaedic operating

Page 38

rooms; is that right?
A. Yes, that is correct.
Q. All right. And, specifically, you wanted to know whether the hospital uses warming blankets or forced air heaters; is that right?
A. Yes.
Q. And Ms. Hogan responded to your initial e-mail on April 21st, and her response says:
"...In more than just ortho, we use both types, depending on the length of the expected surgery..."
Is that her response?
A. Yes.
Q. Okay. And then you then responded to her, it seems shortly thereafter also, on April 21st, and you say:
"...Okay. Thanks. I am doing a review of the forced air type in relation to infection control. Perhaps I could witness one in operation at some point?..."
Is it fair to say that you had not seen a forced air warming system during...in use in an operation prior to the time of this e-mail?
A. No. I had...I had been in...I had been in surgeries to witness before, but was not

Page 39

acutely aware of any warming device as part of that observation, and I have...I have seen a Bair Hugger system outside of the operating room. So this was a follow-up to actually specifically witness the operation of a warming system in the operating room.
Q. And you wanted to see that in the hospital that you work at, correct?
A. That is correct.
Q. All right. And did you, in fact, then go see the forced air warming system in use in your hospital?
A. I did not see it in the operating room in use after this.
Q. All right. Why not?
A. I did not get a response to this e-mail, and the director of perioperative was...is quite busy, and I have tried, as well, in this case not to put any burden on the hospital as a result of my work in this case. So I didn't want to push the issue too much with her.
Q. All right. That brings up another question. As you are being compensated for the research that you're doing and the advice or counsel you are providing in this case, does your hourly consulting fee go to you personally, or does that go

Page 40

to the hospital or to some other entity?
A. That goes me to personally.
Q. And what would you...what amount of money have you been paid thus far in connection with your work on this matter?
A. The amount of money is related to the payment of my first invoice that I referred to earlier.
Q. And do you recall, as you sit here today, what the amount of that first invoice was?
A. No, I don't recall.
Q. Do you have a sense, as you sit here today, what amount of money is still due to you for the other two invoices that have not yet been paid?
A. Yes.
Q. And what is that?
A. I believe it's somewhere in the range of just over $10,000.
Q. Canadian or U.S.?
A. Because I don't have an exact amount, I would say either.
Q. Okay.
A. Yes. It's a rough target.
MS. ZIMMERMAN: And I will now show you...we are up to Exhibit 4...what has been

Page 41

marked as Exhibit 4.

--- EXHIBIT NO. 4: Fragment of LinkedIn correspondence between Michael Keen and Dan Koenigshofer, dated April 17 and April 26, 2017

BY MS. ZIMMERMAN:
Q. And I will represent to you that this has been produced to us by counsel for 3M. I recognize that the picture on this document is Dan Koenigshofer. Is this the LinkedIn contact that you referenced in connection with your response to number 2 on the subpoena?
A. Yes, it is.
Q. All right. And you provided this to counsel?
A. Yes, I did.
Q. Did you have any additional LinkedIn correspondence with Mr. Koenigshofer?
A. Not after these dates.
Q. Okay. And this is one of the three correspondence that you referenced in connection with subpoena request number 2; is that right?
A. That is correct.

Q. I will represent to you that Exhibits 3 and 4 are the only two pages of documents that we received from counsel for 3M in connection with this subpoena. Based on the questions and answers that we have gone through over the past 50 minutes or so, is it fair to say that there are some other documents that you have identified and produced to counsel that are responsive to this subpoena, beyond these two pages?

A. Yes.

Q. All right. Do you have any idea, as you sit here right now, why those documents have not been produced to us?

A. No, I do not.

Q. But you did diligently search through your files and produce the responsive documents to counsel for 3M?

A. Yes, I did.

Q. Okay. So we talked a little at the beginning or in the last 45 minutes or so about why it is we are here, and that is so that the plaintiffs that have brought lawsuits in this case have an ability to explore what the opinions are that you offer, because you have been designated as an expert witness on behalf of 3M. And you understand, at

least in some...some reason that we are here is to understand what your opinions are, correct?

A. I understand I am here to represent the opinions of my report, yes.

Q. All right. And do you understand that we have the right to explore the methodologies that you may have employed to reach those opinions?

A. Yes. I don't know the exact details of what you're entitled to do, but asking me about those opinions, I would agree that that was within what I understand.

Q. Okay. And you understand that we have the opportunity to ask you essentially what support you have for the opinions that you intend to offer at potential trial of this matter; is that...do you understand that?

A. I understand it as you tell me right now, yes.

Q. Okay. And does that seem fair, that the plaintiffs should have an ability to understand what support you may have for the opinions you offer so that we can test whether those opinions are grounded in fact?

A. That doesn't surprise me.

Q. All right. And are you prepared to

give that testimony, as we sit here today?

A. I am prepared to give testimony on my report, yes.

Q. All right. And, really, I think what...from the plaintiffs' perspective, what we're getting at is whether or not the conclusions that you have reached or the opinions that you have offered in this matter are supportable, okay?

A. I understand.

Q. All right. And we are here to determine whether or not those opinions are reasonable as well, okay?

A. I understand.

MR. GOSS: Object to form.

BY MS. ZIMMERMAN:

Q. Now, as I understand it, you have not done any biological testing in connection with your work in this matter, have you?

A. I have not.

Q. Okay. And you have done no filtration testing in connection with your work on this matter, have you?

A. I have not.

Q. All right. You have conducted no

particle count testing on this case, have you?

A. I have conducted no particle count testing on this case.

Q. And, in fact, you haven't personally done any original testing in connection with your work on the Bair Hugger matter; is that fair?

A. That is correct.

Q. All right. And would you agree that you have done no...do you know what CFD is?

A. I know what CFD is.

Q. Computational fluid dynamics; is that right?

A. That is correct.

Q. You have done no computational fluid dynamics work or analysis in this matter; is that correct?

A. I have reviewed CFD papers, but I have done no original CFD analysis of my own in this case.

Q. Okay. You have done no calculations of your own in this case, correct?

A. I don't believe I have done any calculations related to this case, other than some conversions between units of measure.

Q. And would that be something like

Celsius to Fahrenheit? Is that the kind of conversions you're talking about?
A. That is a good example.
Q. All right. Are there any other conversions that you can recall that you did with respect to your report in this matter?
A. Other examples might include volume of air, units of energy. Those are a couple of others I can think of right now.
Q. All right. Is it fair to say that your report is largely a recitation of critiques that you may have about various peer-reviewed studies?
MR. GOSS: Object to form.
THE DEPONENT: A component of my report is a review of other studies of which I have provided opinions on.

BY MS. ZIMMERMAN:
Q. Okay. And some of the critiques that you offer are on studies that are not peer-reviewed; is that right?
A. I can't recall at this time which ones are peer-reviewed and which ones weren't, to be honest.
Q. Do you know what peer-reviewed is?

A. Yes, I do.
Q. All right. And what is a peer-reviewed study?
A. Well, it's part of the...a part of the process for formal research and publication of papers in which those are, effectively, peer-reviewed, so...
Q. Why is the peer-review process important?
A. That process, as I understand it, is important from having a third party look at the process by which research and publication was done to have that independent validation.
Q. All right. And you...we looked at your CV in this matter, which is Exhibit 2. You are a member of a number of professional societies; is that right?
A. Yes, I am.
Q. What professional societies are you a member of?
A. I am a member of the Professional Engineers of Ontario. I am a member of Canadian Standards Associations. I am a member of the American Society of Heating, Refrigeration and Air Conditioning Engineers, otherwise known as ASHRAE. I

am a member of the Canadian Hospital Engineering Society, which is not listed on my CV.
Q. Canadian Hospital Engineering Society?
A. Yes, short form CHES.
Q. And do you have a leadership role in that organization?
A. No, I do not.
Q. And do you assist in publications with respect to that organization?
A. No, I do not.
Q. Are you a member of ASME at all?
A. No, I am not.
Q. And that is the American Society of Mechanical Engineers?
A. Yes, it is.
Q. You're aware of the society; you're just not a member?
A. I am aware of the society. I am not a member.
Q. Okay. And we were talking about peer-reviewed publications. ASHRAE puts forth a number of papers. Would you describe the ASHRAE committee process as akin to a peer-reviewed process?
A. Sometimes, sometimes not.

Q. All right. When is it like a peer-reviewed process?
A. I couldn't fully answer all the times that they have peer-review. I just know that there are some papers that they have that are peer-reviewed and some that are not.
Q. With respect to an ASHRAE publication, is it fair to say that the standards are typically written out in a publication and the actual writing is done by a committee of some sort?
A. Yes. The members of the committee write the standard.
Q. All right. And do they exchange drafts of the standard that they are working on?
A. Yes, drafts are exchanged between the committee members.
Q. And is it your understanding that when a standard is ultimately finalized and published, it reflects the consensus about minimum standards for any particular...for whatever the particular chapter may be addressing?
A. Yes. When a standard is published, it reflects the consensus of the committee.
Q. And would you agree that it's a consensus of the committee with respect to minimum

Page 50

standards?
A. Minimum standards are a component of the standards, and sometimes there are clauses that are not just minimum standards.
Q. Okay. Are you a member of any other professional societies besides the ones on your CV and then the Canadian Hospital Engineering Society?
A. No, I don't think so.
Q. Do you have any idea about how many folks in ASHRAE or who specialize in HVAC engineering that 3M may have contacted prior to retaining you in this matter?
A. I have no idea how many.
MS. ZIMMERMAN: And I am going to mark as Exhibit 5 the report that you authored in this matter, and we will be going through this in some detail throughout the course of the day today.

--- EXHIBIT NO. 5: Expert report of Michael Keen, dated June 2, 2017

BY MS. ZIMMERMAN:
Q. Can you look through that and confirm that that is a true and correct copy of the report

Page 51

that you prepared in connection with your work in this matter?
A. Yes. At a quick glance, this appears to be a true copy of my report.
Q. Okay. And the main opinions that you offer in this report, I think that they appear at the bottom of page 5, is that right, the "Bair Hugger potential for risks of contributing to surgical site infections"? And then it goes on to say:
"...This report will review the following areas of potential risk..."
Are those really the main focus of your report in this matter?
A. That is the main focus...at the bottom of page 5, that is the main focus of the scope of the report. There may be some other things that are covered here, specifically the review of studies to measure bacterial contamination. I don't know if that necessarily falls within what is listed in these couple of lines here.
Q. And so a review of the studies that measure bacterial contamination?
A. Correct.
Q. And just at a high level, when you were retained in this matter, what were you asked

Page 52

to do?
A. When I was retained in this matter, I was provided with a number of publications and a list of questions, of which I have responded to in the format of the structure of my report.
Q. And were those articles, and then also the questions that you were asked to answer, provided when you were initially retained in either December of 2016 or January of 2017?
A. They came sometime thereafter.
Q. Shortly thereafter or sometime in the spring?
A. I believe it is sometime in the spring or late winter.
Q. So at the bottom of page 5, you identify two areas that the report will focus on:
"...a. Airborne bacteria passing through the Bair Hugger unit and its filter [and]
b. Disruption of airflow that could increase risk of particles settling in the surgical site..."
I think just now you said that there is, essentially, a (c), which is a review of studies that measure bacterial contamination. Is that an accurate summary of opinions that you intend to offer in this matter?

Page 53

MR. GOSS: Object to form.
THE DEPONENT: I believe that covers the majority of what is included in the opinions in my report.

BY MS. ZIMMERMAN:
Q. All right. Can you show me where in your report you are rebutting opinions offered by Michael Buck, for example?
A. I don't believe I am specifically rebutting opinions by Michael Buck in my report.
Q. Okay. And with respect to...I will skip the bigger one, but with respect to...well, have you been provided a copy of the report from William Jarvis? Here is a hint, he is an infectious disease medical doctor from the United States of America who has offered opinions on infectious disease matters. Have you read his report?
A. I don't believe I have.
Q. All right. And is it fair to say you are not going to be offering any rebuttal testimony with respect to Dr. Jarvis?
A. No, I don't believe I did.
Q. If you haven't seen his report...
A. If I haven't seen it, I haven't

Page 54

provided...
Q. All right. Fair. Have you been provided a copy of the expert report of Jonathan Samet, an epidemiologist, also from the United States of America?
A. I don't recall that name, so I don't believe so.
Q. All right. And is it fair to say you are not going to be providing any expert opinions that are rebutting those offered by Jonathan Samet?
A. I don't believe my report has anything to do with those opinions about Samet
Q. All right. Have you been provided the expert report of Dr. Michael Stonnington? He is an orthopaedic surgeon in the United States of America.
A. I don't recognize that name, so, no, I don't believe so.
Q. All right. And so, I take it from your answer that you won't be providing any rebuttal testimony to Dr. Stonnington's opinions as well?
A. Again, I don't believe I reported...I don't believe I have reported any opinions on that report.
Q. And Stonnington's name doesn't appear

Page 55

in your report anywhere?
A. No, it doesn't.
Q. All right. And so, you have been provided a copy of the report of Said Elghobashi, is that right, or just his deposition?
A. I do have his deposition. I do not recall is report.
Q. All right. Do you know that Professor...Dr. Elghobashi is a professor at University of California, Irvine? Do you know that?
A. No, I don't know.
Q. All right. And it seems, at least as you sit here today, you don't recall if you have been provided a copy of his report at all?
A. I don't recall.
Q. And you have been provided a copy of his deposition but it is not something that you have read at this time; is that right?
A. I have not read it.
Q. Okay. So is it fair to say that you are not here to offer any opinions that are going to rebut those opinions offered by Said Elghobashi?
MR. GOSS: Object to form.
THE DEPONENT: My report doesn't contain any opinions on Elghobashi's reports.

Page 56

BY MS. ZIMMERMAN:
Q. All right. And you understand that, if you were going to rebut opinions that have been offered by Elghobashi, they would need to be contained in your report; is that fair?
A. I haven't included those reports, and I am not sure of the process of the legal proceedings.
Q. Okay. And, in any event, there are no specific criticisms or rebuttals of Elghobashi's report in the report of Michael Keen; is that correct?
A. There are not.
Q. All right. Are you aware that Professor and Dr. Elghobashi is an expert in computational fluid dynamics?
A. No, I am not.
Q. You are not aware, as you sit here today?
A. No.
Q. All right. Is it fair to say that you would defer to others on issues of computational fluid dynamics?
A. On the details of CFD, I would refer to others. I do not purport to be an expert on CFD.

Page 57

Q. Which I believe leaves Dan Koenigshofer, and you have been provided Dan Koenigshofer's report; is that correct?
A. Yes, I have.
Q. All right. And you have also been provided a copy of Dan Koenigshofer's deposition; is that correct?
A. Yes, I have.
Q. All right. And you have also discussed Dan Koenigshofer's deposition to some extent with Dan Koenigshofer himself, correct?
A. No, I have not discussed the contents of his deposition, just the sort of generalities of the event.
Q. All right. He relayed some comments about the process; is that fair?
A. Yes.
Q. All right. But, other than that, there was no discussion about the details of his opinion or yours; is that fair?
A. There is no discussion about mine or his opinion between us.
Q. And I take it that you and Mr. Koenigshofer perhaps run into each other from time to time at professional conferences and the like; is

Page 58

that fair?
A. Yes, we do.
Q. All right. Would you consider him a colleague of yours?
A. Yes, I would.
Q. Okay. Have you worked together on projects in the past?
A. We have worked together on ASHRAE matters, but not outside of ASHRAE matters on projects.
Q. Okay. In your report, there is no specific section that is titled "Rebuttal". And so, I think one of the things we will be faced with over the course of the next number of hours is determining which portions of your report are specifically rebutting other expert reports. I take it, from the last few minutes of our discussion here, that you are principally rebutting expert testimony offered by Dan Koenigshofer; is that fair?
A. I am principally in my report providing opinions on my review of the documentation I was provided.
Q. Okay. As you sit here today, are there any specific rebuttals of Mr. Koenigshofer's report that are contained within your report?

Page 59

A. I did not focus on a rebuttal as my focus of my report, but primarily on my own opinions.
Q. Okay. And I think one of the things I left off in our instructions at the beginning is, if you ever want to take a break...this is not an endurance contest, and most of us are here until tomorrow, in any event. So if you would like to take a break...you know, sometimes people break about every our, hour and a half...just let me know.
MR. GOSS: I wouldn't mind a bathroom break whenever you're ready.
MS. ZIMMERMAN: Sure. Now is fine.
MR. GOSS: Okay.
MS. ZIMMERMAN: Take a break.

--- upon recessing at 11:18 a.m.
--- A BRIEF RECESS
--- upon resuming at 11:29 a.m.

MICHAEL KEEN, resumed
CONTINUED EXAMINATION BY MS. ZIMMERMAN:
Q. Mr. Keen, let's discuss your education. What is your educational background?
A. I have a bachelor's degree in applied science and mechanical engineering from the

Page 60

University of Waterloo, and I have an executive master's in business administration from Queen's University.
Q. All right. Did your business administration degree involve any additional engineering courses?
A. The MBA course...the MBA program did have courses that were similar to what was in engineering. An example would be statistics. So that was in both my engineering curriculum and in the MBA curriculum, as an example.
Q. So did you take statistics again, or did you get credit for having taken it as an undergrad?
A. I took it again.
Q. Okay. Did you take any other engineering course work in connection with your master's degree?
A. There may have been some similar overlap, but, otherwise...otherwise not part of the MBA curriculum, not specifically anything targeted at engineering.
Q. Okay. And have you given...your bachelor's degree in engineering, have you had experience working as an engineer?

Page 61

A. I have had experience in design engineering work.
Q. All right. And you are a licensed engineer in Canada?
A. I am a licensed professional engineer in the province of Ontario within Canada.
Q. And you are a member of the professional engineering community in Canada; is that fair?
A. I am a member of the Professional Engineers of Ontario, as referenced on my resume.
Q. Okay. Have you had any experience ever in designing a medical device?
A. I have not had experience in designing a medical device.
Q. Did your education, in connection with your bachelor's degree, involve any courses on ethics?
A. Yes.
Q. What did you learn about ethics in your undergraduate degree?
A. Do you have a specific question? It was a big course.
Q. It was a large course? Was it a required course?

Page 62

A. It was a...it was...that is a good question. I think it was a required course and it was a full-term course, so...
Q. All right. And, in fact, the professional engineers of Ontario have ethical guidelines and a code of ethics that governs professional engineers; is that right?
A. Yes, that is correct.
Q. All right. And you would agree that the code of ethics for professional engineers in Ontario establishes a basic guide for professional conduct; is that right?
A. Yes, it does.
Q. All right. And you would agree that the code of ethics for professional engineers in Ontario imposes duties on practitioners? Do you agree with that?
A. I am actually not sure what you mean by that.
Q. Would you agree or would you be surprised to learn that the professional engineer society for Ontario expects practising engineers to comport themselves with a specific code of ethics?
MR. GOSS: I am just going to object that ethics are beyond the scope of his opinions

Page 63

in this case, and that ethics is not a proper subject matter for expert testimony.

BY MS. ZIMMERMAN:
Q. You can answer.
A. So I am aware the Professional Engineers of Ontario have a code of ethics, and I couldn't give you the details of all the workings of that organization in respect of ethics.
Q. All right. But you understand, as you sit here today, that there is a code of ethics that governs practising engineers in Ontario, right?
A. Yes, I am aware of that.
Q. Okay. And you are a member of that organization, correct?
A. I am a member of that organization.
Q. And you understand that there is an interest by this organization in ensuring ethical practice by practising engineers in Ontario, right?
A. Yes.
Q. And you understand that that imposes, essentially, a code of conduct on practising engineers here in Ontario, correct?
A. Yes.
Q. And you would expect that the same

Page 64

code of ethics would apply, whether the practising engineer was an independent contractor or, for example, working for a corporation, correct?
A. Yes.
Q. And so, you would agree with me that the code of ethics governing engineers here in Ontario governs engineers working for corporations as well, correct?
A. Yes.
Q. Would you agree that it is the duty of a practitioner to evidence fidelity to public needs here in Ontario?
MR. GOSS: Objection, vague, and continuing objection to ethics as a subject matter.
MS. ZIMMERMAN: You can have a standing objection to that, Counsel.
MS. ZIMMERMAN: Thank you.
THE DEPONENT: Could you restate the question, please?

BY MS. ZIMMERMAN:
Q. Sure. Let me see if I can move on and provide some additional context. Would you agree that a practising engineer should regard the duty to

Page 65

public welfare as paramount? Do you agree with that statement?
A. Yes.
Q. There is nothing more important than public safety; does that seem fair?
A. I agree that...my understanding of the duty of an engineer, that public welfare is paramount, yes.
Q. Okay. And you would agree that a practising engineer should keep the public welfare in mind whenever they are making...whenever they are offering opinions from an engineering standpoint?
A. Yes.
Q. All right. And you would agree or you would understand that the code of ethics that governs engineers here in Ontario also governs testimony that a practising engineer may offer as a witness before court; do you understand that?
A. I don't know the details of how that code of ethics would apply.
Q. Okay. Do you understand whether an engineer here in Ontario is permitted, ethically, to serve as a witness on professional engineering matters without ensuring they have adequate knowledge of the matter they are providing testimony about?

Page 66

A. No, I am not aware of the details of that.
Q. Okay. Are you aware that the professional engineers of Ontario are required to maintain honour and integrity of the profession without fear or favour and expose before proper tribunals unprofessional, dishonest or unethical conduct by any other practitioner?
A. I am not aware of the specific quote that you have just read.
Q. All right. Does that seem fair to you?
A. Can you repeat it, please?
Q. Sure.
"...That a practitioner shall maintain the honour and integrity of the practitioner's profession and without fear or favour expose before the proper tribunals unprofessional, dishonest or unethical conduct by any other practitioner..."
A. I am sorry, I can't comment whether that is consistent with the Professional Engineers of Ontario.
Q. Do you disagree with that?
A. I can't comment on whether that is

Page 67

consistent with what is in the code of the engineers of Ontario.
Q. All right. Would it seem unreasonable to you, as you sit here today, to have an ethical code of conduct that requires practising engineers to expose before proper tribunals unprofessional, dishonest or unethical conduct?
A. Again, I am not able to comment on that detail.
Q. All right. So you don't know, as you sit here today, whether that may be a code of ethics that presently governs the testimony that you may be providing in this matter today?
A. I am not aware of the exact language that...whether...as you have mentioned it, whether that is consistent with the Professional Engineers of Ontario code of conduct.
MS. ZIMMERMAN: Exhibit 6.

--- EXHIBIT NO. 6: Printout from the website of Professional Engineers Ontario, re code of ethics

BY MS. ZIMMERMAN:
Q. And, Mr. Keen, I am showing you what

Page 68

has been marked as Exhibit 6, which comes from the Professional Engineers of Ontario website. It is something that we printed off here. Have you ever seen...have you ever logged onto their website before?
A. Yes, I have logged on the website before.
Q. All right. And are you aware that there is a code of ethics that govern professional engineers of Ontario?
A. Yes, I am aware there is a code of ethics.
Q. All right. And you would agree then and you are aware that that code of ethics imposes duties on practising engineers here in Ontario, correct?
A. Correct.
Q. And you are aware then that those duties include a duty with respect to society, correct?
A. Sorry, I find that question vague.
Q. That is fine. If you would like to turn to the third page, at the bottom, it says:
"...The Code of Ethics is a basic guide for professional conduct and imposes duties on

Page 69

practitioners, with respect to..."
And the first thing listed is "society". Do you see that?
A. Yes, I see that.
Q. All right. So you would agree with me then that the code of ethics governing professional engineers in Ontario imposes a duty on practising engineers with respect to ethics and professional conduct for society as a whole; is that right?
A. Yes.
Q. Okay. And turning onto the next page underneath "Professional Engineers Ontario Code of Ethics, Section 77 of the O. Reg. 941", this also outlines the code of ethics of the association. And this is an association of which you're a member, correct?
A. That is correct.
Q. All right. And it shows under number 1, sub (ii) that there is...the practitioner is to act at all times with fidelity to the public needs. Do you see that?
A. Yes, I see that.
Q. All right. And under number 2 it says:

Page 70

"...A practitioner shall,
i. regard the practitioner's duty to [the] public welfare as paramount..."
Do you see that?
A. Yes, I see that.
Q. All right. And then, under sub (iii) to number 2 it says:
"...A practitioner shall not express publicly, or while the practitioner is serving as a witness before a court, commission or other tribunal, opinions on professional engineering matters that are not founded on adequate knowledge and honest conviction..."
Do you see that?
A. Yes, I do.
Q. All right. And so, that requires that a professional engineer here in Ontario be sure that they have adequate knowledge prior to providing an opinion or serving as a witness before a court, correct?
A. Correct.
Q. And that would be what is ethically required by the Professional Engineers Ontario code of ethics, correct?

Page 71

A. Yes.
Q. And then, turning to the last page, number 8, it shows that:
"...A practitioner shall maintain the honour and integrity of the practitioner's profession and without fear or favour expose before the proper tribunals unprofessional, dishonest or unethical conduct by any other practitioner..."
Do you see that?
A. Yes, I do.
Q. And so, you would agree then, as a member of this organization, that you also have the ethical obligation to maintain the honour and integrity of your profession without fear or favour and expose before proper tribunals unprofessional, dishonest or unethical conduct by any other practitioner, correct?
A. Yes.
Q. And those are obligations that you take with you as you provide testimony in this matter in this deposition today, correct?
A. Yes.
Q. All right. Turning back to your report, which is Exhibit 5 in this matter, you have

Page 72

recently reviewed this report in preparation for your testimony today; is that right?
A. Yes.
Q. And you reviewed the report with counsel; is that correct?
A. Yes.
Q. How much time did you spend preparing for your deposition today?
A. It could be somewhere in the realm of approximately 20 hours.
Q. And was that time that you spent so far this week?
A. Yes.
Q. And what did you review to prepare during those 20 hours this week?
A. So I reviewed my report. I reviewed referenced publications within that report. I reviewed depositions that were provided to me, and I did some Google searches, as I answered previously.
Q. And one of the depositions that you read this week was the deposition of Dr. Kuehn from Minnesota; is that correct?
A. Yes. I read part of that deposition, correct.
Q. All right. How much of his

Page 73

deposition did you read?
A. Approximately half.
Q. And how long did that take you?
A. I don't recall exactly.
Q. Which part of his deposition did you read?
A. The first half, approximately.
Q. And did you read that because you were directed to read that by counsel?
MR. GOSS: Object to form.
THE DEPONENT: Yes. I was provided...I was provided that deposition as reference reading in preparation for deposition.

BY MS. ZIMMERMAN:
Q. To help you understand what you might expect today; does that seem...was that your understanding?
A. Yes, that is correct.
Q. All right. And in reading the deposition of Dr. Kuehn from this Monday, did you learn facts that you had not previously known about the litigation in this case?
A. There was information...the deposition was new to me, and I don't believe I have

Page 74

read anything previous by Tom Kuehn. So everything within it was, effectively, new information to me.
Q. Did you take any notes on the deposition of Dr. Kuehn?
A. No, I did not.
Q. Did you highlight the deposition of Dr. Kuehn?
A. No, I did not.
Q. What information specifically was new to you?
MR. GOSS: Object to form.
THE DEPONENT: I don't have a specific piece of information. As I said, the entire deposition was new to me, as I have not read Tom Kuehn's previous information.

BY MS. ZIMMERMAN:
Q. Have you been provided a copy of Dr. Kuehn's report?
A. No, I don't believe I have a copy of Dr. Kuehn's report.
Q. All right. And forgive me, I am sure I have this listed. Do you have the reports of any of the other defence expert witnesses?
A. So, as you had asked previously, I am

Page 75

not fully aware of who all the defence expert witnesses are, and I only know for certain that Settles, I think is the name, right, Settles...
Q. Right.
A. ...I have that report.
Q. Have you been provided the expert report of Dr. Borak?
A. I am not familiar with that name, so I do not believe so.
Q. All right. What about...I think it might be Timothy Holford? I might have the first name wrong. I know the last name is Holford.
A. No, I don't believe I have a Holford document.
Q. All right. What about Antonia Hughes?
A. No, I don't believe I have a Hughes document.
Q. How about Michael Mont?
A. No, I don't recognize that name.
Q. All right. What about Wenzel?
A. No, I don't have a document by Wenzel.
Q. You do have a report from Settles; is that right?

Page 76

A. I do have a report from Settles.
Q. And is it just a single report from Settles?
A. Yes. I have a PDF and a Word document. I believe they are both identical documents, though.
Q. Have you been provided a copy of the report of John Abraham?
A. No, I don't believe so.
Q. What about Samsun Lampotang? And I am not sure if I am pronouncing that right.
A. Based on how you have pronounced it, I don't believe I have that one.
Q. It doesn't ring a bell? How about Hannenberg?
A. No, I don't recognize that.
Q. Had you previously received Jim Ho's expert report?
A. No, I did not.
Q. You received his deposition?
A. I received his deposition.
Q. But not his report?
A. I do not have his report.
Q. And I think you said, with respect to Dr. Kuehn, you were provided his deposition this

Page 77

week, but you have not seen his report; is that fair?
A. That is correct.
Q. What about Ulatowski?
A. I don't recognize that name.
Q. All right. So it seems, of thirteen...and I will represent to you that there were thirteen experts proffered by counsel for 3M; you are one of those thirteen, that leaves twelve. And you received one of those expert reports?
A. I am aware of Settles as one of those expert reports, and I am not aware of any others.
Q. Okay. So I take it you don't have any critiques of any of those expert reports, because you have never read them?
A. I referenced Settles in my report, but I don't have critiques of the other reports.
Q. By the way, do you have any critiques of Dr. Settles' report?
A. My report contains opinions that I have made in reference to his report, and I do not have any separate critiques.
Q. Which portion of your report would you say is a critique of Settles?
MR. GOSS: Object to form.
THE DEPONENT: If you refer to page 18 of

Page 78

my report, I have a reference to Settles in my report of his paper.

BY MS. ZIMMERMAN:

Q. And I see that this appears to follow a similar format to critiques or commentary that you offer on some other studies, many of which were peer-reviewed. You understand that the Settles report is not peer-reviewed, correct?

A. I am not aware right now that... whether it is peer-reviewed or not.

Q. Okay. We will ask you to assume, as we sit here today, that the report that Settles prepared was prepared in connection with this litigation, and, to my knowledge, has not been submitted for or accepted in a peer-reviewed journal, all right?

A. Okay.

Q. Are you...in this paragraph on page 18, are you providing criticism of the report offered by Settles?

A. In this paragraph, I am referring to some of the findings of Settles' report. That is all.

Q. All right. You note that Settles

Page 79

uses Schlieren imaging technique. Are you familiar with Schlieren imaging?

A. Yes.

Q. Is that a technique that you use in your profession?

A. No, it is not.

Q. All right. What is your understanding about the Schlieren imaging technique?

A. My understanding of the technique, as I reviewed it in this case, has to do with images that show heat patterns.

Q. Is it something that was part of your undergraduate training or course work, for example?

A. I actually don't recall.

Q. Nothing that you have used before, I take it?

A. I have not conducted Schlieren technique myself.

Q. Do you have any knowledge, as you sit here today, about how Schlieren works?

A. I do not know the details of how it works.

Q. Okay. So you would defer to someone who has training and education in the use of Schlieren imaging technique; is that fair?

Page 80

A. Yes, I would.

Q. Okay. And are you aware, from reading Dr. Kuehn's, from Minnesota, deposition that the Schlieren imaging technique is something that is not routinely taught anymore?

A. I do not recall that.

MR. GOSS: Object to form.

BY MS. ZIMMERMAN:

Q. And, in any event, it is not something that you use in your job at the hospital today?

A. I do not use Schlieren in my day-to-day job at the hospital.

Q. Given that you would defer to others on Schlieren imaging technique, you're not in a position, as you sit here today, to know whether Settles has performed that technique accurately or not; is that fair?

A. I am not aware whether he performed it accurately or not.

Q. Now, we talked a little bit before our break about the main opinions that you have offered in this matter, and I believe that those start at the bottom of page 5 of your report.

Page 81

MR. GOSS: Object to form.

MS. ZIMMERMAN: Basis?

MR. GOSS: I think his opinions are actually at the end of the report, items 9(a) through (g).

BY MS. ZIMMERMAN:

Q. So, 5 outlines what the report will review, and it breaks out subpart a) airborne bacteria passing through the Bair Hugger unit and the filter, and subpart b) disruption of airflow that could increase risk of particles settling in the surgical site. I think that, when we were discussing these earlier, you said that you're also going to be, through the course of this report, reviewing various studies that measure bacterial contamination. Is that consistent with your understanding?

A. That is correct.

Q. You have seen a Bair Hugger in person, right?

A. Yes, I have.

Q. Do you know what model you saw?

A. I don't recall the exact model number.

Q. Do you know what colour it was?

Page 82

A. Yes.
Q. What colour?
A. It was a bluish-purple colour.
Q. All right. And I take it that you saw, or at least intentionally looked for the Bair Hugger in an operating room for the first time this year; is that fair?
A. Yes.
Q. All right. You may have seen it from time to time when you have been in operating rooms in the past, but this year is the first time you specifically looked for a Bair Hugger in an operating room?
A. Yes. This year is the first year I specifically looked for one.
Q. All right. And if the 775 is the model that is most prevalently used in an operating room now and it is bluish-purple in colour, would it be your assumption that what you saw was probably a model...a 700 series model?
A. I wouldn't assume what model I saw.
Q. Okay. Do you know if you ever saw a 500 series Bair Hugger?
A. Again, I don't recall the exact model number that I saw.

Page 83

Q. Have you ever seen a Bair Hugger that is white in colour?
A. I don't believe I have.
Q. All right. And have you ever seen... I take it then that you haven't seen the 200 series Bair Hugger either?
A. I don't know what the 200 series is off the top of my head.
Q. Are you aware that the Bair Hugger devices go back to...I mean, over 20 years at this point?
A. I don't know the exact time that the Bair Hugger has been in use.
Q. All right. And I take it then that you have not seen the original Bair Hugger machine; is that fair?
A. I have not seen the original Bair Hugger machine.
MS. ZIMMERMAN: I am going to show you here what we have been marking as Exhibit 7.

--- EXHIBIT NO. 7: Image of Bair Hugger 200 series machine, showing sign titled "Important Notes"

Page 84

BY MS. ZIMMERMAN:
Q. And I will represent to you that this is a photo taken from the front of a Bair Hugger 200 series machine. I take it that you have not seen this before?
A. No, I don't believe I have.
Q. All right. Do you see at the bottom of the...there is a section here, it says "Important Notes", and it says:
"...Caution: This machine not intended for use in the operating room..."
A. I see that note.
Q. All right. Are you aware that the original Bair Hugger machines were not intended to be used in the operating room?
A. No, I am not aware of that.
Q. This is the first time that you are learning about that, today?
A. Yes, it is.
MS. ZIMMERMAN: All right. I am showing you what has been marked as Exhibit 8.

--- EXHIBIT NO. 8: Image of Bair Hugger 200 series machine warning label

Page 85

BY MS. ZIMMERMAN:
Q. And I will represent to you that this is a photograph of that same 200 series machine. And I will direct you specifically to warning number 5, which says:
"...The possibility of airborne contamination should be considered if patients with infected wounds are treated with the Bair Hugger..."
Do you see that?
A. I see that note.
Q. All right. And I take it that you have not seen this warning prior to your deposition here today?
A. I have not.
MR. GOSS: I am just going to object on the ground that he is not offering any warnings, opinions, and he lacks foundation.
MS. ZIMMERMAN: All right.

BY MS. ZIMMERMAN:
Q. And you haven't seen this before today?
A. I have not seen this before today.
Q. You would agree, based on that

Page 86

warning, that the risk of airborne contamination causing infections was something that was known, at least at the time the warning was placed on that machine, correct?

MR. GOSS: Objection, lack of foundation, not offering any warnings, opinions. You can answer if you understand the question.

THE DEPONENT: I am aware that you have represented this is a picture of a warning on the unit. That is all I am aware of.

BY MS. ZIMMERMAN:

Q. All right. And the warning does, indeed, say that the possibility of airborne contamination should be considered, correct?

A. Yes, it reads...

MR. GOSS: Objection, incomplete, lack of foundation. Go ahead and answer.

THE DEPONENT: Yes, that is part of what number 5 reads.

BY MS. ZIMMERMAN:

Q. All right. And that is not information that you were provided prior to your deposition here today?

Page 87

A. I have not seen this note before today.

Q. Right. And have you been provided any information about the warnings as they exist on the Bair Hugger today?

A. Sorry, could you repeat that question?

Q. Have you been provided copies of or pictures of any warnings that exist on the Bair Hugger machine today, in 2017?

MR. GOSS: I am just going to object that it is outside the scope of his opinions. You can answer.

MS. ZIMMERMAN: To the extent that he understands that the ethics that govern his testimony today require that he be provided all the information that underlie the opinions that he offers in this matter. It is not outside the scope of what he is being asked to provide testimony about.

MR. GOSS: And I respectfully disagree, but you can answer the question.

THE DEPONENT: No, I don't believe I provided...would have been provided with any warnings relative to the Bair Hugger.

Page 88

BY MS. ZIMMERMAN:

Q. So you don't know, as you sit here today in 2017, whether there remains a warning on the machine about the risk of potential airborne contamination or not, fair?

MR. GOSS: Same objection.

THE DEPONENT: I have not seen this warning before, and so I don't...and I don't know if it is still on the machine.

BY MS. ZIMMERMAN:

Q. Okay. Well, I will ask you to assume, as we go forward, that those warnings were removed from the 505 and 700 series devices. Would that be information that is relevant, as you offer testimony today, about filtration and potential disruption of unit directional flow in the operating room?

MR. GOSS: The same objection.

THE DEPONENT: So it is new information. I would need to consider it as to how it would affect my opinions.

BY MS. ZIMMERMAN:

Q. Have you been provided documents that

Page 89

would tend to show that 3M misled customers about filtration efficiency?

MR. GOSS: Objection to form, assumes facts not in evidence.

THE DEPONENT: Sorry, could you restate that question?

BY MS. ZIMMERMAN:

Q. Sure. Have you been provided any documents that would tend to show that 3M or Arizant misled customers about filtration efficiency?

MR. GOSS: Same objection.

THE DEPONENT: So, I have been provided with a website link that critiqued the Bair Hugger, and...you know, I am not sure if that answers your question, but if I believe that is where you are going...if I believe that is what your question refers to, I have been provided a website of a source that critiques the Bair Hugger.

BY MS. ZIMMERMAN:

Q. Okay. And that is not the truthaboutbairhugger.com or something?

A. I don't recall the exact website. It

Page 90

has been a while since I looked at it.
Q. All right. You know, I should have asked, do you know Dr. Scott Augustine?
A. I have heard the name but I have not...I do not know him.
Q. All right. Have you heard the name prior to your involvement in this matter?
A. No, I did not.
Q. All right. And what is your understanding of who Dr. Scott Augustine is, and why we might care about him in this litigation?
A. My understanding is he is the one that originally came up with the Bair Hugger idea, and that he is involved now on the plaintiffs' side of this case.
Q. And someone has told you that he is involved in the plaintiffs' side of the case?
A. Yes.
Q. Okay. Well, I will ask you to assume that that is not correct, and that he has not been retained by any of the plaintiffs, that he has not... that he is not involved in this case. That would be inconsistent with what you have heard prior to coming to this deposition?
MR. GOSS: I just ask you not to disclose

Page 91

any conversations that you had with counsel.

BY MS. ZIMMERMAN:
Q. And I understand that puts you in kind of a tricky spot. I am not asking for what Mr. Goss has told you. But, to the extent I am asking you to assume that Dr. Augustine is not involved with the plaintiffs' case, that would be inconsistent with your understanding before you arrived here today?
A. So if you are telling me that he is not involved, then maybe I misunderstood that.
Q. Okay. Would you consider yourself an expert on filtration?
A. I have experience in dealing with filters and how filters are applied in healthcare applications and some of the standards around filters.
Q. And does your experience include the filter media itself?
A. I mean, I have experience and understanding about the filter assembly, including its media and...in my experience.
Q. And would you agree that...when you're talking about a filter, would you agree the

Page 92

terms "high efficiency" by themselves are meaningless?
A. I would say that the term "high efficiency" is a qualitative one that is not an official reference for the rating of filters, but is commonly used as a sort of layman term.
Q. All right. And would you agree that, in order to provide meaningful information about high efficiency, you need to know not just high efficiency but also the size of the particle that will be filtered out or captured by the filter, as well as the rate of efficiency of the capture? Does that make sense?
MR. GOSS: Objection, vague.
THE DEPONENT: Can you restate that question, please?

BY MS. ZIMMERMAN:
Q. I will do my best. I have heard, by way of example, you could have a cattle fence...
A. Sorry?
Q. A cattle fence that is high efficiency for keeping cattle in a field.
A. Cattle?
Q. Cattle.

Page 93

A. Sorry, I heard "kettle".
Q. Sorry, cattle.
A. Cattle.
Q. Cows.
A. Yes, cows, yes.
Q. And a fence with perhaps barbed wire might well be high efficiency at keeping cows in a field. That same fence may not be high efficiency for something smaller than a cow; do you agree with me?
A. I am not going to talk about the efficiency of cow fences, but I understand what you are saying.
Q. All right. And, similarly, if you are playing tennis someplace and there is a fence around a tennis court, the fence may be high efficiency at containing tennis balls inside the tennis court, but other things may well be able to get through that fence; does that make sense?
A. I understand your description.
Q. Okay. Or, in Minnesota, where we have very large mosquitoes, we have screens on our windows with the intent, at least, to keep the mosquitoes out of our houses, but there may well be other things that are able to travel through the

screen. So it may well be a window screen that is high efficiency for mosquitoes, but that doesn't mean it's impervious to other things. Do you understand that as well?

A. I understand that, and I am sorry for your mosquitoes.

Q. Yes. We're all sorry for mosquitoes. I suspect you have some of the problems that we have.

A. We also have mosquitoes.

Q. So the purpose of providing those perhaps cumbersome examples is to focus in on the words "high efficiency". Would you agree with me that saying "high efficiency" without additional qualifiers is not meaningful in discussing a filtration level?

A. Again, I would say that the term "high efficiency" I have seen commonly used as a generic layman's term for describing a filter, but it is not an official term that is used in the rating of filters.

Q. And someone that would be making decisions about whether to use a filter or which type of filter might...ought to be selected would need information probably beyond what a layman would need about the efficiency of a filter; does that seem

fair?

MR. GOSS: Objection, form, calls for speculation.

THE DEPONENT: The specification of a filter should rely on the official ratings.

BY MS. ZIMMERMAN:

Q. All right. And official ratings are determined...MERV puts out official ratings for filters; is that right?

A. MERV is a procedure for rating filters.

Q. Right. And what MERV does in rating filters is it talks both about the size of the particulate that will be filtered and the effectiveness of the filter at removing that size particle; is that right?

A. That is correct.

Q. Okay. And would you agree with me that, without either one of those modifiers, either the size of the particle or the effectiveness of the filter, the terms "high efficiency" on their own are not going to provide a professional with adequate information to make a decision pursuant to the MERV guidelines, for example?

A. I would agree that the term "high efficiency" does not provide adequate guidance as to the MERV rating of a filter.

Q. All right. And would you agree with me that "high efficiency" could tend to confuse a consumer who may not be as educated in the MERV ratings as someone such as yourself?

MR. GOSS: I am just going to object, we went from professional to consumer.

THE DEPONENT: I don't know if it would confuse a consumer.

BY MS. ZIMMERMAN:

Q. Are you familiar with the term "HEPA"?

A. I am familiar with the term "HEPA".

Q. And what does HEPA stand for?

A. You are going to test my memory. I am trying to remember the acronym. No, I don't want to hazard a guess right now. I have seen it many times, but I don't recall right now the acronym.

Q. But you would agree that HEPA is actually a term of art in filtration, correct?

A. HEPA is a term of a filter, yes.

Q. All right. And it describes a

specific filtration level and efficiency, correct?

A. It does.

Q. So a filter can't be called a HEPA filter unless it meets the MERV standards for what it means to be HEPA, correct?

A. I am a bit challenged on that, since the MERV rating recently removed HEPA from its rating scale.

Q. Right.

A. But I understand what a HEPA filter is.

Q. What is your understanding of a HEPA filter on the MERV scale now? Is there an equivalent?

A. There isn't an equivalent on the MERV scale now.

Q. What used to be the equivalent of a HEPA?

A. The HEPA was above a MERV 16 level on the rating scale in the previous publication of the standard.

Q. And the MERV rating has now removed HEPA. There is no classification beyond 16; is that correct?

A. That is correct.

Page 98

Q. And, in any event, you would agree that it would be inappropriate for someone to call a filter a HEPA filter if it were capable of removing only 50 percent of particles at .3 microns, by way of example?

A. I wouldn't classify the rating of a HEPA that way.

Q. Well, how would you classify a HEPA rating?

A. When it used to be in the MERV scale, there was a range of particle sizes, of which an average particulate efficiency rating was taken across a range of sizes. And, as a result of that, it would be determined whether it was HEPA or not.

Q. Right. And is it your understanding that HEPA filters were 99.97 percent efficient at removing particles .3 micrometres and larger? Is that consistent with your understanding of what HEPA means?

A. Again, there are efficiency ratings across size distributions for HEPA filters. And, without them in front of me right now, I can't quote them.

Q. Okay. Do you know what the standard filtration and efficiency rate is for a HEPA filter?

Page 99

A. I have seen it in tables and refer to those tables, but I cannot quote it from memory.

Q. Is it a fair generalization that HEPA is, essentially, one of the highest efficiency rating filters for very small particles?

A. HEPA is a...one of the higher efficiency rating filters that we apply.

Q. By the way, do you have experience at all with clean rooms for use in, for example, consumer electronics?

A. I do not.

Q. All right. Do you understand that manufacturing of silicon wafers or things like that inside of a consumer electronic, they have clean rooms where they control carefully for any kind of particulate in the air?

A. Yes, I am familiar with that.

Q. All right. And you would agree, as you sit here today, that, in fact, clean rooms where they manufacture these kinds of component parts for consumer electronics are more rigorously controlled than operating rooms?

MR. GOSS: Objection, lack of foundation.

THE DEPONENT: I understand that clean rooms for microprocessor manufacture are designed differently than operating rooms, for different objectives.

Page 100

BY MS. ZIMMERMAN:

Q. All right. At any rate, you would agree that it is appropriate to communicate accurate filtration efficiency information, and that somebody such as yourself at a hospital relies on the filtration efficiency information being accurate?

MR. GOSS: Objection, outside of the scope of his opinions in this case.

THE DEPONENT: Sorry, am I supposed to proceed to answer that?

MS. ZIMMERMAN: Yes.

MR. GOSS: You can answer it if you understand it.

THE DEPONENT: Yes. I...in the use of filters in a hospital application, I rely upon the efficiency information that I am provided.

BY MS. ZIMMERMAN:

Q. All right. And you assume that the efficiency information that you are provided is, in fact, accurate, correct?

Page 101

MR. GOSS: Same objection.

THE DEPONENT: Yes. When we purchase filters, we would assume that the information that we are provided is accurate.

BY MS. ZIMMERMAN:

Q. All right. And you rely on the filter manufacturer to provide that information to you, correct?

A. Yes, we do.

Q. And it would trouble you, I trust, in your role at the hospital if you were to learn that the efficiency was significantly lower than it was represented to be, correct?

MR. GOSS: Same objection, object to the incomplete hypothetical.

THE DEPONENT: If I were provided a filter for hospital use that was misrepresented, then that would trouble me, yes.

BY MS. ZIMMERMAN:

Q. And have you seen internal company e-mails that show, in fact, that Arizant and 3M did

not want to tell the customers about the true filtration efficiency on the Bair Hugger?

MR. GOSS: Objection to form, assumes facts not in evidence, beyond the scope of his opinions in this case.

BY MS. ZIMMERMAN:

Q. There is no evidence at this point. I am asking if you have been, in fact, provided the e-mails that indicate that that was the company's intention.

MR. GOSS: I object to the characterization of documents, lack of foundation. You can answer if you understand it.

THE DEPONENT: I don't have documents that say that.

BY MS. ZIMMERMAN:

Q. So you haven't been provided with any e-mails that would say, for example, we do not want to disclose the actual filtration level of the Bair Hugger machine? You haven't been provided with those e-mails?

MR. GOSS: Asked and answered.

THE DEPONENT: I don't have those e-mails.

BY MS. ZIMMERMAN:

Q. All right. And would that be important information to you as you are considering and rendering the opinions that you have been offered to render in this case?

A. The opinions that I provided on filers were based on documents I was provided.

Q. And if you weren't provided all the relevant documents, you would agree that the opinions that you have offered in this case are incomplete, correct?

MR. GOSS: Objection to form, calls for speculation.

THE DEPONENT: I have offered opinions based on the documents that I have been provided and referenced, and those opinions are stated in my report.

BY MS. ZIMMERMAN:

Q. And let's turn back to the report in front of you, so Exhibit number 5, and let's start at the back of the report, the references section, just

so that we are clear here, and I think that that starts on page 23. Section 10 is "Reference listing". So the first thing is the "ASHRAE Standard 170, Ventilation of Health Care Facilities, 2013". Do you see that?

A. Yes, I see that.

Q. We are on the same page?

A. Page 23?

Q. Yes.

A. Yes.

Q. All right. Good. The second...and you find that to be authoritative, and that is something that you relied upon in rendering your opinions, correct?

A. I relied upon the standard for my opinions, yes.

Q. Okay. And then you go through...and I won't, at least at this point, go through every single thing that is listed, but, harkening back to the beginning of your deposition, these references are the sum total of what you relied upon in offering your opinions in this case; is that correct?

A. These reference the documents I relied upon my opinions. I also relied upon my experience and training, obviously, to render those

opinions as well.

Q. Okay. So these references plus your training and experience are what you rely on in offering your opinions, correct?

A. Yes.

Q. And there aren't additional written materials that you are relying upon to offer the opinions that you have outlined in this report, correct?

A. That is correct.

Q. And you would agree that these materials are materials that were provided to you by counsel for 3M, correct?

MR. GOSS: Object to form.

THE DEPONENT: Some of these materials were provided to me by counsel, some of them I had already, and some of them I found in my own search.

BY MS. ZIMMERMAN:

Q. I have two different colour of highlighters. Could you highlight for me on your exhibit, let's say orange for the documents that were provided to you by 3M, and yellow for those documents that you found on your own?

Page 106

A. Can you clarify for process, do you want me just to highlight them, or do you want me to speak when I am highlighting, or...
Q. Well, the court reporter will have the original document and that will be...
A. So I don't need to speak; I could just highlight?
Q. You can just highlight if you like.
MR. GOSS: And if you don't remember, I would ask you just not to highlight it.
THE DEPONENT: Okay. So orange provided by counsel?

BY MS. ZIMMERMAN:
Q. Yes, and yellow is what you found on your own.
A. And how would you classify the ASHRAE Standard 170, which I was already in possession of? I didn't go searching for...obviously I was already in possession of, so...
Q. Well, were you also provided by counsel?
A. No.
Q. No. Okay. Well, then you handed in...

Page 107

A. It is classified that I found it as my own?
Q. Yes.
A. Okay. Because I didn't go looking for it as part of this.
Q. Sure, sure. You already had it. Okay.
A. I already had it.
Q. We will put that in your independent...
A. So that is yellow as well?
Q. ...research. Yes.
A. Okay.
MR. GOSS: Just to make sure that I am clear, yellow is he either found it or had it, orange is 3M?
MS. ZIMMERMAN: Yes.
MR. GOSS: And blank is he doesn't remember.
MS. ZIMMERMAN: Do you folks want to take a break while he is working on this? I don't have an objection.
MR. GOSS: Do you want to break for lunch at some point?
MS. ZIMMERMAN: I suppose that is the

Page 108

disadvantage of starting late. Yes, at some point we should.
MR. GOSS: We are off the record.

--- upon recessing at 12:28 p.m.
--- A BRIEF RECESS
--- upon resuming at 12:38 p.m.

MICHAEL KEEN, resumed
CONTINUED EXAMINATION BY MS. ZIMMERMAN:
Q. We are back on the record, at least for a while, and right before we took a break, you were highlighting the references that you found versus those which were provided to you by counsel. And just for clarity on the record, could you tell us which fall under which category, please?
A. Sure. So the yellow category, being ones that I had in my possession prior to this case or that I found on my own, I have highlighted references (a), (b), (e), (f), (g), and (k). In reference to...sorry, references that were provided by counsel, I have highlighted these in orange. These are references (h), (j), (n) as in "Nancy", (o), (p), (s) as in "Sam", (t), (u), (w), (x), (y), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh). And

Page 109

those that I have left blank, I do not recall whether they were my own or from counsel, and those include the rest of them.
Q. All right. Thank you very much.
A. I will return your highlighters.
Q. Thank you. So you would agree that the vast majority of the references that you can recall the source, they were provided by counsel for 3M; is that correct?
A. The majority of the references were provided to me by 3M counsel.
Q. All right. And then, of those that you had previously or did a search for, and that is a, b, e, f, g and k, how many of those did you need to go find for the first time in connection with this case? Any of them?
A. (g) and (k), I found for the first time in relation to this case.
Q. All right. And so the rest...the other ones were either articles or publications that you had on the shelf in your office, right?
MR. GOSS: Of the yellow highlighted ones?
MS. ZIMMERMAN: Yes, exactly.
THE DEPONENT: Of the other highlighted

ones, the others are publications by either CSA or ASHRAE, actually.

BY MS. ZIMMERMAN:

Q. Okay. All right. And so, as you sit here today, other than perhaps one Google search where you were trying to reconfirm your understanding of the definition of the word "asepsis", is it fair to say that you are not...you can't recall any particular independent research you did specific to this case?

A. I had mentioned it was more than one Google search.

Q. Okay.

A. That was the one I could recall.

Q. All right.

A. So there was a number of Google searches on, you know, as I mentioned, primarily definitions and some other information.

Q. Okay. And would you agree you were, at least in some part, in large part even, taking 3M's counsel's word for it or representations that these were the articles that you should focus on?

MR. GOSS: With respect to the orange ones, correct?

MS. ZIMMERMAN: Correct.

THE DEPONENT: The orange ones were provided by counsel for review and consideration for my opinions in my report.

BY MS. ZIMMERMAN:

Q. Okay. And you were relying on 3M to provide you those articles that would be relevant for your opinion, is that fair, beyond those that you already had in your office?

A. And some of those...some of them were provided to me by 3M counsel, some of them I already had, and some of them...some of the information that I relied upon came from my own independent search.

Q. Okay. Is that good engineering practice?

MR. GOSS: Objection, vague.

THE DEPONENT: Can you clarify what you mean?

BY MS. ZIMMERMAN:

Q. Sure. So, as an engineer, would you agree engineers solve problems?

A. I would agree that engineers solve problems, yes.

Q. All right. And would you agree that, at least, that is the objective of a mechanical engineer, for example?

A. It's one of the potential...one of the potential objectives of a mechanical engineer is to solve problems.

Q. Right. Identify the problem and hopefully solve the problem?

A. That is a potential objective that a mechanical engineer could work on.

Q. All right. And, as you approached the problem presented to you by counsel for 3M... well, what is your understanding of the problem that was presented to you by 3M?

A. 3M provided me with some documentation and a list of questions of a scope that they wanted me to address my opinions on that scope. And so that...the answer to that list of questions in reference to documents that I either had, found or provided by 3M counsel are found in my report.

Q. And will you agree that, as engineers approach...identify and approach problem-solving, they are...engineers are supposed to be objective?

A. I took an objective approach to the development of my report. I am not sure if I agree

with the generality of your question, though.

Q. Okay. But you don't agree that, generally, engineers should be objective in trying to solve problems?

MR. GOSS: Object to form.

THE DEPONENT: I don't believe, in all instances, engineers approach problems objectively.

BY MS. ZIMMERMAN:

Q. Okay. And would you agree, in taking a bundle of literature from 3M, that you may not have been objective in approaching this problem?

MR. GOSS: Object to form, asked and answered.

THE DEPONENT: As you have already asked, I have...and as I have answered, I have...I took an objective approach to my development of my report.

BY MS. ZIMMERMAN:

Q. All right. And it is your testimony, as you sit here today, that having...so there are 34 citations in your report; does that look about right? You have about 26 letters of the alphabet and we add

27, 28, 29, 30, 31, 32, 33, 34.
A. That appears to be approximately the right number.
Q. All right. And of those 34, at least 19 are articles or documents provided by 3M?
A. At least 19 of those documents were provided to me by 3M.
Q. All right. And it may be more than just 19. Just...as you sit here today, just not completely sure about where you first came across a couple of these non-highlighted articles; is that fair?
A. Some of the non-highlighted articles may have been provided to my 3M counsel.
Q. Okay. All right. And yet your testimony, as you sit here today, is that you took an objective approach to solving this problem?
MR. GOSS: Objection, asked and answered.
THE DEPONENT: As answered previously, I have taken an objective approach to answering...to the preparation of my report.

BY MS. ZIMMERMAN:
Q. Okay. What other independent research have you done on the Bair Hugger?

MR. GOSS: Are you asking beyond what is in the scope of his report?
MS. ZIMMERMAN: I mean, I would like to know specifically what independent research has been done. And we know what he had in his office. For sure we know some number of articles that were provided by 3M. What was independently discovered?
THE DEPONENT: So, as I believe I have mentioned to you previously, I had the information provided to me by 3M counsel. I had...

BY MS. ZIMMERMAN:
Q. And you would agree with me, by the way, that that is probably not objective, right?
MR. GOSS: Object to form, calls for speculation.
THE DEPONENT: I would not speculate whether it's objective or not. It was information that was provided to me that I took an objective review of. I also had information in my possession, as mentioned, and I also did additional search for information on my own.

BY MS. ZIMMERMAN:
Q. Okay. And, as to the additional search for information, you are not...you can't really recall, as you sit here today, other than the asepsis piece, what specifically you went looking for; is that fair?
A. No, that would not be correct.
Q. Okay. Well...and I apologize if I've got it wrong. Please tell me what else you did to independently research this issue.
A. If I could give you an example, based on what we have been discussing, I highlighted item (g) in the reference listing as one...as a document that I found on my own. That reference (g) is a document that I have produced as part of my independent search.
Q. Okay. And reference (g) has to do with understanding MERV ratings for ANSI and ASHRAE; is that right?
A. Yes.
Q. Is anything about that specifically related to the Bair Hugger?
A. In my opinions rendered on the Bair Hugger, I talk about filtration issues, and I used this document as a reference tool in rendering my

opinions on filtration.
Q. Okay. Is there anything else that you can think of, as you are sitting here, that you did to independently research the issues presented?
A. The Price document listed in (k) is another one that I found through my research that found...that had some relevant information that I relied upon for my opinions.
Q. The Critical Environments Engineering Guide?
A. That is correct.
Q. Okay. Is that a peer-reviewed journal?
A. No, it is not.
Q. Did you ever Google Bair Hugger?
A. Yes, I did.
Q. And what did you learn from your Google search?
A. I can't recall all that I have learned from that. I looked at various websites on Bair Hugger, images of Bair Hugger. There were some YouTube videos on Bair Hugger that I looked at in that search.
Q. Can you recall who...were they videos that were put out by the Blackwell Burke law firm, or

Page 118

do you know who produced the videos?
A. I don't recall who produced the videos that I looked at.
Q. Were they associated...you don't know if they were associated with Dr. Scott Augustine?
A. I do not recall.
Q. Okay. Have you spoken with any of the employees at 3M about the Bair Hugger product?
A. I have not.
Q. All right. Have you done any...I mean, we talked a little about PubMed. Have you done any other searches for peer-reviewed studies about the Bair Hugger?
A. In my search, I have looked at other studies. The studies that I found relevant have been included in my...that I have used to refer to my opinion have been included in my reference listing. I know that some of those blanks, and I can't remember which ones exactly, are ones that I have found as part of that search.
Q. All right. You would agree with me that operating room ventilation systems and designs for healthcare facilities are intended to provide a comfortable environment for patients, healthcare workers and visitors, while at the same time

Page 119

diluting, capturing and exhausting airborne contaminants, including potentially infectious airborne agents, right?
A. I would agree with what you said in that statement, although I am not sure it's entirely all inclusive. But within the limits of what you have said, I would agree with.
Q. And as one of the folks at a hospital that is charged with...well, let me ask you, you are one of the folks at your hospital that is charged with maintaining the HVAC system at your hospital; is that right?
A. No. I am currently not responsible for the maintenance of HVAC systems. I had previously held a position where I provided leadership and operation of maintenance to the hospital, but that is not my current role.
Q. What is your current role?
A. My current role is senior director of planning and development.
Q. And what does that entail?
A. That role primarily entails the planning and project management lead of redevelopment projects at the hospital through the various stages of planning, design, implementation, occupancy or

Page 120

post-occupancy.
Q. And does that include renovations at the hospital, for example.
A. That includes renovations at the hospital.
Q. Does it include new buildings, perhaps, that are built as part of the hospital campus?
A. That includes new buildings.
Q. Does it include evaluation or repairs of the existing structure?
A. Sometimes it can involve evaluation and repair of existing structure as well.
Q. All right. And so, is it your responsibility then to kind of oversee large-scale projects that take into account these renovations or new construction, or perhaps retrofitting existing structures happens from time to time?
A. Yes, that would be part of my responsibility.
Q. All right. And so, as part of your responsibility at the hospital, would you agree that you draw on your previous experience in maintaining the HVAC system for a hospital?
A. Yes, I do draw on my previous

Page 121

experience.
Q. All right. And would you agree, in your role currently and in the past, that a patient's safety is a paramount concern?
A. Yes, I would agree a patient's safety is a paramount concern.
Q. And you are familiar with ASHRAE Standard 170, correct?
A. Yes, I am.
Q. And you have been involved in helping to develop that standard, correct?
A. Yes, I have.
Q. All right. And would you agree that that defines the minimum ventilation system design requirements for various portions of a hospital?
A. The ASHRAE Standard 170 defines minimum requirements for ventilation systems in healthcare facilities in the jurisdiction in which it applies.
Q. And ASHRAE 170 applies to your hospital here in Ontario?
A. ASHRAE 170 does not specifically apply to my hospital here.
Q. Okay. And has your hospital, in fact, adopted measures that exceed those standards

Page 122

outlined in standard 170?
MR. GOSS: Objection, vague.
THE DEPONENT: In the design of our hospital, we have designed features that exceed what is contained in 170.

BY MS. ZIMMERMAN:
Q. And is one of those design requirements in your hospital a requirement that HEPA filters be used for all...well, for certain types of operating rooms?
A. The Canadian standard for HVAC in healthcare facilities requires HEPA filtration on the supply air for both orthopaedic and transplant surgeries.
Q. All right. Would you agree that the ventilation system is intended to provide environmental control of the operating room?
A. Yes, I would agree with that.
Q. And you would agree that the ventilation system design is also intended to provide some comfort for the people inside the operating room?
A. Yes, I would agree with that.
Q. All right. Would you agree that the

Page 123

minimum ventilation system design requirements also deal with asepsis?
A. Yes, I would agree with that.
Q. All right. And that was one of the searches that you did in preparing for this deposition, correct?
A. Yes, it was.
Q. You would agree that "asepsis" means clean?
A. No, I don't think that is how I would define "asepsis".
Q. How would you define "asepsis"?
A. I thought you would ask me that.
Q. You have been leading up to it all day, so...
A. I know. I should have...
MR. GOSS: I can't wait to hear.
THE DEPONENT: My understanding of asepsis, it is the...it is the management of contamination within an environment.

BY MS. ZIMMERMAN:
Q. So it is a management of contaminants inside of an environment?
A. Correct.

Page 124

Q. All right. And is that generally thought to at least attempt cleanliness?
A. I wouldn't define it as cleanliness.
Q. All right. Would you agree that it is an attempt to manage pathogens?
A. I would agree with that, yes.
Q. All right. Would you agree that it is an attempt to manage bacteria?
A. Where those pathogens and bacteria are controllable by airborne means, yes, I would.
Q. All right. And you are aware that pathogens and bacteria can be airborne, correct?
A. Correct.
Q. And you would agree that a hospital is intending to promote asepsis as much as possible, correct?
A. I would agree that a hospital is intending to promote asepsis. Sorry, I am hung up on your words "as much as possible", as contemplated...
Q. Maybe you will go to law school next.
A. I don't want to answer it on the "as much as possible piece", but, yes, it is certainly the goal to control...to provide asepsis.
Q. And, if possible, you would agree that a hospital would try to completely eliminate any

Page 125

pathogens, right?
A. No, and that probably goes to my "as much as possible", that there is a certain level that risk can be managed to that does not necessarily mean complete elimination.
Q. Is it a certain level that risk can be managed to, or a certain level that risk is managed to?
MR. GOSS: Objection, vague.
THE DEPONENT: Yes. I don't understand the question, so can you restate that question?

BY MS. ZIMMERMAN:
Q. I will do my best. So, for example, and perhaps it is a bad example, but in the consumer electronics industry where they have clean rooms and they are manufacturing, you know, wafers for use in laptops and cell phones and all the rest of it, it is my understanding that they have a threshold that far exceeds, in terms of cleanliness and asepsis, that which we tolerate in our hospitals; would you agree with that?
MR. GOSS: I just object, lack of foundation, and outside his expertise. If

you know the answer, you may answer.
THE DEPONENT: So, as I have answered previously, I know that the two environments have different designs for achieving different objectives.

BY MS. ZIMMERMAN:
Q. Okay. Do you think it would be possible to have a hospital that is completely free of pathogens?
A. I do not believe that it is possible to be completely contaminant free, 100 percent.
Q. But, in your previous and current role, as someone who has been involved with and perhaps now supervises those folks that are charged with the maintenance of the HVAC system, you understand the goal is to promote asepsis, correct?
A. I would agree the goal is to promote asepsis.
Q. All right. And why is that?
A. As part of that goal, to provide an environment that is safe for patients and staff, and manages, to appropriate levels, the risk of infection.
Q. And you would agree that folks that

work in a hospital in a role like yours would ideally like to...
A. Sorry, in a what like mine?
Q. In a role...
A. In a role, thank you.
Q. ...like the role that you have at your hospital, that you would prefer to see zero infections in your hospital, correct?
A. I would prefer to see zero infections.
Q. Right. I don't think that that is probably too scandalous. You agree that the ASHRAE standards and Standard 170 define different filtration requirements for different areas in a hospital, correct?
A. That is correct.
Q. And an operating room has, for example, a different filtration level or requirement than a patient recovery room, for example?
A. Off the top of my head, I can't remember the patient recovery room filtration level.
Q. Okay.
A. But the standard defines the filtration level for both those spaces.
Q. All right.

A. And the standards for your hospitals here in Ontario requires an even greater, a more efficient, more sophisticated filtration mechanism for operating rooms where orthopaedic surgeries are performed, correct?
MR. GOSS: Objection to form.
THE DEPONENT: The filtration requirements that are applied in this jurisdiction under the CSA document have different filtration levels for operating rooms for orthopaedic surgery.

BY MS. ZIMMERMAN:
Q. And they are, in fact, more stringent or more efficient than the standards outlined in ASHRAE Standard 170, correct?
A. ASHRAE Standard 170 calls for a MERV 14 secondary filter for an operating room, and does not specify a different filtration level for an orthopaedic operating room. CSA Z317.2 calls for a HEPA filter in the secondary filtration for an orthopaedic operating room.
Q. And are you on the committee that decided on this standard here in Ontario?
MR. GOSS: The CSA standard?

MS. ZIMMERMAN: Yes.
THE DEPONENT: I am a member of the subcommittee for 317.2, yes.

BY MS. ZIMMERMAN:
Q. All right. And did your committee decide that these additional filtration requirements are required in Canadian hospitals for orthopaedic surgeries because you recognize a greater risk of infection in those procedures?
A. I believe, to the best of my memory, that clause has been in effect since before my time on the committee, and so I do not recall the rationale for implementation of that clause.
Q. So, as you sit here today, you don't know why the committee decided orthopaedic surgery... and did you say transplant surgeries?
A. And transplant surgeries.
Q. As you sit here today, you don't know why orthopaedic surgery and transplant surgery require this more strenuous filtration?
A. I don't know why that...the rationale that the committee used to include those clauses, as I believe they were before my time.
Q. All right. Would you agree it stands

Page 130

to reason that the committee likely identified those patients as patients that are at higher risk?
MR. GOSS: Object to form, calls for speculation, lack of foundation.
THE DEPONENT: Again, I don't know the rationale to which that committee made that determination.

BY MS. ZIMMERMAN:
Q. Do you know, as you sit here today, if orthopaedic surgery patients and transplant patients are at higher risk of infection than other surgical patients?
A. Yes. I am aware that those patients have different risks and...of different risk of infections, yes, I am aware of that.
Q. Different risks or higher risks?
A. I would say different risks.
Q. So you disagree with the notion that they are at higher risk of infection?
A. I am not going to comment on whether they are higher or lower risk. I know that they have different risk considerations of infection in surgery.
Q. All right. Are you aware of what

Page 131

kind of treatment might be required should an orthopaedic surgery patient or a transplant surgery patient contract an infection?
A. No, I am not familiar with the treatments of an orthopaedic patient that has an infection.
Q. All right. Do you know if, for example, a transplant patient contracted an infection if they may be at risk of losing the transplanted organ?
A. No, I am not fully aware of the risks of the implications.
Q. Okay. So, as you sit here today, you are not sure why the committee decided that these two groups of patients required some additional measures in the operating room, but there are two subsets of patients, transplant patients and orthopaedic surgery patients, where the filtration standards are higher than that called for by ASHRAE Standard 170; is that right?
A. Yes.
Q. Okay. Would you agree that the fact that, at least in Ontario, a HEPA filter is required instead of a MERV 14, indicates that you want less airborne particles in the operating room?

Page 132

MR. GOSS: Object to form.
THE DEPONENT: I would agree that the requirement, as required by CSA, is to have a HEPA filter.

BY MS. ZIMMERMAN:
Q. Okay. And that is not the requirement that is called for in ASHRAE Standard 170, correct?
A. Correct. As answered previously, the requirement for ASHRAE 170 is a MERV 14 filter.
Q. Okay. And that is not just...well, do you know, is it just Ontario or is it all of Canada?
A. The standard applies to all of Canada.
Q. All right. And do you know why Canada has adopted this more stringent standard?
A. No, I do not.
MR. GOSS: Object to form.

BY MS. ZIMMERMAN:
Q. And you would agree that properly designing, installing and maintaining an HVAC system will result in reducing the risk of infection to

Page 133

patients, right?
A. Yes.
Q. In fact, that is included in your report, right?
A. I don't recall exactly where, but I agree with the statement, yes.
Q. So, in your report, you spend some time outlining different factors in the design of a ventilation system, and you start out at the bottom of page 2 outlining temperature as one of those characteristics. Do you see where you start with that?
A. Yes, I see that clause.
Q. All right. And you note that systems here should be capable of maintaining the operating room within a temperature range of 18 to 23 degrees Celsius or 20 to 24 degrees Celsius during a normal operation, and you provide two different citations there, (b) and (c). (b) and (c) are both documents that you had prior to becoming involved in this case; is that right?
MR. GOSS: Are they (b) and (c)...
MS. ZIMMERMAN: I'm sorry, (a) and (b).
MR. GOSS: ...or...yes.
THE DEPONENT: Correct.

BY MS. ZIMMERMAN:
Q. And they are both...they are the ASHRAE Standard 170, and the CSA standard Z317.2, correct?
A. Correct.
Q. And why are the temperature ranges important?
A. Temperature range is important for a number of reasons. One involves the comfort of the patient, one involves the comfort of the...one involves the comfort of the staff and healthcare providers. Temperature of the patient is also related to patient safety and the potential risk of contracting infection. Temperature is also an important consideration in its relativity with humidity, to manage moisture content and condensation. Temperature is also an important component for the proper operation of different pieces of equipment.
Q. And you detail some additional thoughts or opinions that you may have or facts... I am not quite sure how to characterize them...with respect to humidity here. I think I just heard you testify that the temperature of the patient is related to safety with respect to their infection

risk; is that right?
A. That is correct.
Q. What is the basis for that statement?
A. So my understanding is that a patient that goes into a hypothermic condition has a greater risk of contracting an infection.
Q. All right. And where do you derive that understanding?
A. That understanding came from review that I did of information during the preparation of my report.
Q. Okay. And so, prior to your involvement in this particular case, you didn't have an understanding about whether or not patient temperature played a role in potential infection concerns, correct?
A. No. Actually, I did have that understanding but it was more of a general understanding.
Q. All right. And to be clear, you have been designated by counsel for 3M as an expert in this case. And so what I am here to understand... what I need to understand today are what are the factual underpinnings for the opinions you're going to offer. So if you...if it is your opinion that

patient temperature impacts a patient's infection risk, I want to know specifically what is the basis for that belief.
MR. GOSS: Just before he answers that, I am just going to stipulate on the record he is not going to offer any opinions about normothermia as an expert, the risk or benefits of normothermia. But I understand your question to be, what is the basis for his understanding. And, to that extent, you can answer if you are able to.

BY MS. ZIMMERMAN:
Q. And, you know, what we're really going to be doing, not to show my hand completely, but throughout the next couple of hours is going through, because some of the statements that you provide in this report have citations and some of them do not. And, to the extent that it is something that you are not citing to someone else, I want to know that it is either something that you have personal training and experience or expertise in, or what the basis is for the opinion or statement that you are making.
So, to the extent that that is an opinion

that you're offering at this deposition, that patient safety...or patient temperature is related to their safety or their ability to contract an infection, I want to know specifically what that comes from.
MR. GOSS: And just to repeat my objection, I don't think...he is not going to offer any opinions relating to normothermia, but to the extent that he had an understanding on the relationship between patient temperature and infection risk, then I will let him describe, to the best of his ability, the basis for that statement.
MS. ZIMMERMAN: I am going to object to the speaking objection. I think that your stipulation that he will not be providing any testimony about the benefits or risks of normothermia is well taken, but, beyond that, if the witness is having a hard time understanding my question, he can let me know.
THE DEPONENT: Okay. I understand your question, and I have a general understanding of the benefits of normothermia during surgery. I also have referred to documents in my references that state that as well,

Page 138

and I need to find that reference if you want me to.

BY MS. ZIMMERMAN:

Q. Well, so...and I will direct you specifically. Right before you get to "Humidity" on page 3 it says...you say...not I say. It says:

"...While most of these factors would drive lower space temperatures in the operating room, keeping the patient warm is important factor for patient comfort, prevention of hypothermia and prevention of nosocomial infection..."

There is no citation there. And I understand that, generally speaking, you have references at the back, but you have specific endnotes listed throughout the course of this report. And so what I want to know is what specifically and precisely are you relying upon to make the statement that prevention of hypothermia and prevention of nosocomial infection is in any way related to keeping a patient warm.

A. Okay. Just give me a minute to review my report.

Q. If you had relied on something, it would be cited right there, as you have placed

Page 139

endnotes throughout the report, correct?

A. I have made an effort wherever possible to include references.

Q. All right. Have you been provided the depositions of Dr. Sessler or Dr. Kurtz in this matter?

A. I do have a document referenced here by Dr. Sessler.

Q. All right. But do you understand that they have been deposed several times in connection with the lawsuits pending in the United States?

A. I do not know about the deposition of Dr. Sessler.

Q. Right. And they were not...those depositions were not on the list of depositions that you listed at the beginning of your testimony here today, correct?

A. Correct.

Q. All right. So, as you sit here today without additional time to amend your report, you're not able to point to a specific citation for this proposition that keeping a patient warm is important and will help prevent nosocomial infection, correct?

A. I can't from memory right now recall

Page 140

the reference. I believe there was one, and without time to review my report to find that reference, I can't do that from memory right now.

Q. Okay. And so, at any rate, while somebody else may have offered that opinion based on, you know, perhaps a test that they have done or some other kind of training or experience, it's not something that you know about specifically and personally, as you sit here today, correct?

A. I...

MR. GOSS: Object to form. Go ahead.

THE DEPONENT: As I have answered previously, I do have general knowledge through my experience that prevention of hypothermia with patients is beneficial for prevention of infection.

BY MS. ZIMMERMAN:

Q. Okay. And what is that based on?

A. That is based on my work in the hospital interacting with operating room staff.

Q. Okay. And so you have been told by an anaesthesiologist, or by whom that this is good practice?

A. I don't recall exactly which

Page 141

operating room staff I've had those discussions with over the years.

Q. Okay. And this all took place...you heard about prevention of hypothermia and its relation to prevention of infection prior to your involvement in this litigation?

A. Yes.

Q. All right. From who?

A. Again, from operating room staff within the hospital.

Q. How does normothermia reduce infections?

A. I am not fully aware of the details of how it does.

Q. All right. And you're not a medical doctor, correct?

A. I am not a medical doctor.

Q. So you're not going to be offering opinions at trial in this matter about the physiological response of a body to temperature and to pathogens, correct?

A. No, I will not. I will refer to others.

MR. GOSS: [inaudible]

MS. ZIMMERMAN: All right. And counsel

has already stipulated that you are not going to be offering opinions about normothermia; is that correct, Counsel?
MR. GOSS: Yes, but he is not going to be testifying about the benefits of normothermia, you know, other than what he has got as his background experience in this report.
MS. ZIMMERMAN: All right. And I guess, you know, I still need to know specifically what the basis for this statement is.
MR. GOSS: So if you have a different answer or a more detailed answer, you can provide it.
THE DEPONENT: As I provided, I have general information by my experience, and I believe that I have referred to documents that I have also reported that within the list of documents that I have.

BY MS. ZIMMERMAN:
Q. Do you know, as you are sitting here today, what a PJI is?
A. No, I do not.
Q. All right. I will ask you to assume

that it is a periprosthetic joint infection. Have you heard that term used before this case?
A. Yes, I have.
Q. All right. And have you heard that term used as you have worked on committees addressing the needs of orthopaedic surgery patients in an operating room?
A. Yes, I have.
Q. All right. Do you know if normothermia reduces PJIs?
A. I do not know specifically, since I am not really...of the PJI term. So I don't know specifically if that is one of the infections that it produces.
Q. Right. And you understand...or do you understand that PJIs can be caused by a number of different kinds of pathogens?
A. Again, I don't...I am not familiar with PJIs, and so I would refer to somebody who has that expertise.
Q. Okay. So you would defer to an infection disease doctor, for example, with respect to PJI issues?
A. Yes, I would.
Q. Also to an orthopaedic surgeon, for

example?
A. Yes, I would.
Q. Okay. Taking a step, actually, up on page 3, your opinion here says that:
"...Patient warming units such as the Bair Hugger do not contribute significantly to the overall cooling load..."
What is your basis for that opinion?
A. That basis was on the review of the various heat sources in an operating room and the heat generated by a Bair Hugger and the overall air supply for an operating room.
Q. Do you know how many watts are put out by the Bair Hugger?
A. I have been provided some information that has the wattage of the heat provided, yes.
Q. All right. Do you know specifically, as you sit here right now, what the wattage is of the Bair Hugger?
A. It varies, I think, and it varies by model, but on average it's somewhere in the range of 400 to 450 watts of heat generation.
Q. All right. And would that information be important for someone such as yourself, or whomever is dealing with the HVAC

system, to know?
A. Yes. The heat sources would be important to know.
Q. All right. And you agree with me that it would be important to know the heat sources specifically, and also how much heat is being produced by each of those sources, right?
A. I'm sorry, what is the context of your question?
Q. All right. So in designing an HVAC system...let's start just very basically. You have designed HVAC systems before for an operating room?
A. I have participated in design for HVAC system, yes.
Q. Have you ever done...been solely responsible for such a design?
A. No.
Q. All right. Do you rely on others to assist you in making determinations about the appropriate HVAC design in a hospital operating room?
A. I do.
Q. Who do you defer to?
A. I defer to our mechanical engineering design consultants.
Q. Okay. Do you know if, for example,

Dan Koenigshofer has designed HVAC systems in an operating room before?
A. Yes, I believe he has.
Q. All right. And would he be an appropriate person for you to collaborate with with respect to designing the HVAC system in an operating room?
A. Yes.
Q. He would. Would you feel comfortable designing an HVAC system for an operating room on your own?
A. No.
Q. And, as I understand it, ASHRAE contemplates that the HVAC system has two filters, correct, prior to having the air arrive in the operating room; is that right?
A. That is correct.
Q. All right. And what are those filters; do you know?
A. Yes. There is a pre-filter and a secondary filter.
Q. Do you know what MERV rating the pre-filter has?
A. Yes. The table requires a MERV 7 for the pre-filter for an operating room.

Q. All right. And do you know what the requirement is for the secondary filter?
A. Yes, a MERV 14 filter as we previously discussed.
Q. Okay. And where does the air enter the operating room?
A. The air enters the operating room from diffusers in the ceiling.
Q. All right. And then the air is directed down towards the floor; is that right?
A. The air enters from the ceiling, and there are different types of diffusers that are applied throughout the spectrum of the operating room.
Q. All right. And you would agree that there is probably a different arrangement of diffusers, depending on which hospital you may be looking at in a given day, right?
A. I have seen different arrangements in different hospitals, yes.
Q. Different hospitals use a different arrangement, and that is...the differences are standard; would you agree with that?
A. I don't understand your question.
Q. It's probably not a good question.

There is no one standard for what the diffuser arrangement must be; is that right?
A. No. There is standard minimum requirement for the design of the diffuser arrangement, which allows further flexibility beyond that standard.
Q. All right. And have you been involved with designing an HVAC system and these diffusers in operating rooms in the United States?
A. Yes, I have.
Q. Which ones?
A. I believe there was a facility in Georgia that I assisted the design on.
Q. Any others?
A. I don't believe there are any other U.S. ones, to my recollection.
Q. And who did you work with on the Georgia project?
A. There was an engineer from H.H. Angus & Associates.
Q. Do you happen to remember who the engineer was?
A. I don't remember the name, sorry.
Q. About how long ago was that?
A. That was approximately 22 years ago.

Q. Was that part of your college studies?
A. No.
Q. Okay. Is that one of your first jobs after you finished your graduate work, or...
A. It was one of my first jobs after graduate work, yes...sorry, after my undergraduate.
Q. Between undergraduate and graduate work?
A. Correct.
Q. Okay. How big was the team that worked on that project?
A. I don't recall.
Q. But, in any event, it was prior to your graduate course work, correct?
A. Correct.
Q. Okay. And you worked with other folks in determining what kind of HVAC system was used and how to arrange the diffusers; is that right?
A. Yes.
Q. Okay. What else did that project involve?
A. Other areas of the hospital as well.
Q. Okay. And so, you are aware from... are you aware from this project what standards are in

Page 150

the United States for arrangement of the diffusers...
A. Yes, I am...
Q. ...in an operating room? You are. And what are the standards?
A. Standard 170, ASHRAE 170, is the standard that dictates the minimum requirements for the diffuser arrangement in an operating room in the United States in the jurisdictions that 170 is applied.
Q. Right. Do you know how many jurisdictions have adopted ASHRAE 170?
A. I've heard the number before and it is somewhere approximately in the realm of two-thirds of the States, I believe, to three-quarters of the States.
Q. Let me ask this: So you are involved with ASHRAE and you have been involved with at least one hospital project in the United States. Canada has different standards. Why were you involved with ASHRAE?
A. ASHRAE is a very large well-respected organization in the HVAC field. My interest in the Canadian standards for HVAC design in Canada in healthcare facilities led me to an interest in understanding and benchmarking with the ASHRAE

Page 151

standard, which is applied internationally beyond the United States, and is a reference document that is used for the Canadian standard.
Q. Is it fair to say that the Canadian standard wants to be at least as good as what ASHRAE outlines is required?
A. No, I wouldn't necessarily say that.
Q. Are there areas that are outlined in ASHRAE Standard 170 where the Canadian group has said, "We don't need to be quite that exacting"?
A. There are many different clauses within the standards that differ on different points.
Q. Okay. Do they...are you aware of any that relate to HVAC filtration in operating rooms?
A. Yes. As we discussed previously, the differences in orthopaedic and transplant surgery is a difference in the filtration levels.
Q. Is there anything beyond the filtration level required in transplant surgery operations and orthopaedic surgery?
A. I believe the current editions...the primary filter bank is a MERV 7 and the secondary... sorry, and the primary filter bank in the CSA document is a MERV 8.
Q. Okay. Instead of MERV 14?

Page 152

A. No, the primary.
Q. Primary is 8?
A. In the ASHRAE document, I believe the current edition is a 7, and the CSA current edition, I believe it's an 8.
Q. All right. So you have somewhat more strenuous filtration requirements at both levels in Canada, it seems?
A. Higher rated filters in both primary and secondary.
Q. All right. And HVAC requirements under standard 170 also require a recirculation of air for operating rooms; is that correct?
A. No. The standard allows for recirculation.
Q. It allows for it. It doesn't require recirculation?
A. That is correct.
Q. So would the standard allow for 100 percent new air to be taken in from outside?
A. The standard has a minimum requirement for outdoor air...
Q. Of?
A. ...but no maximum requirement. The ASHRAE 170 standard requires four air changes of

Page 153

outdoor air, as a minimum.
Q. Right.
A. But there is no requirement on the maximum side for outdoor air.
Q. All right. And that is air exchanges per hour, correct?
A. Air exchanges per hour.
Q. Okay. And that is generally how we talk about air exchanges in the ASHRAE standards, right?
A. Yes.
Q. Okay. Would you agree that you would expect the cleanest air in the operating room to be that air that is coming immediately out of the diffuser near the ceiling?
A. Not necessarily.
Q. When would that not be the case?
A. I mean, the distribution of contaminants in an operating room is not an exact sort of predictive science. And so there are different areas in that operating room that could have cleaner air than other parts of the room. And it is, again, not exact, so I wouldn't go to predict where that cleanest air is.
Q. All right. So there could be

Page 154

particulates, essentially, anywhere in an operating room; is that fair?
A. That is correct.
Q. All right. But the air that is coming out of the distal end of a dual filtered HVAC system, you would hope has now been filtered not once but twice, correct?
A. It has gone through both the primary filter bank at MERV...for an ASHRAE 170...
Q. 7 or 8?
A. A MERV 7, and has gone through the secondary filter bank at MERV 14 before it reaches the diffusers.
Q. All right. And assuming that those filters are working as designed and represented, you would expect the vast majority of particles and contaminants to have been filtered out prior to coming through the diffuser, correct?
MR. GOSS: Object to form.
THE DEPONENT: I would expect that that air had been filtered consistently with the efficiencies of those rated filters.

BY MS. ZIMMERMAN:
Q. All right. And, assuming that those

Page 155

filters are working as designed and intended, you would assume that the air is...what air would be cleaner than the air that comes immediately out of the diffuser in an operating room?
A. Again, the distribution of particles in an operating room isn't an exact science, and so the concentration of particles at any given point in an operating room is hard to predict. So where the cleanest air might be in an operating room is not easy to predict where.
Q. And is that because particles are not static inside of an operating room?
A. Some particles are static and some are in motion.
Q. And HVAC engineers and the folks that are responsible for making sure that those systems are designed and working properly are aware of these potential particles in the operating room, correct?
A. Correct.
Q. All right. And given that awareness, they design dual filtration prior to the air arriving in the operating room, correct?
A. Yes, I don't think we refer to it as dual filtration. I mean, it is a...there are two filtration banks, as I have described, in the

Page 156

standard. And so those two filtration banks are designed for the supply of air to an operating room.
Q. All right. And after passing through not one but two filter banks and then entering through the diffuser, the air is intentionally directed towards the floor, correct?
A. Not for all diffusers, no.
Q. Would you agree that the majority of diffusers direct air from the ceiling to the floor of an operating room?
A. Certainly a portion of them do.
Q. A portion or the majority?
A. I couldn't say the majority.
Q. Where, besides the ceiling, would the diffusers be located?
A. They would all be located in the ceiling.
Q. All right. So where else would the diffusers be directing the air?
A. There are different types of diffusers that have a vertical throw but don't necessarily have the same vertical trajectory towards the floor, if I am making myself clear.
Q. I'm afraid I'm not sure that I am understanding you. So the diffusers are...

Page 157

A. Maybe if you restate the question in a different way so that I can...
Q. Sure. So the diffusers are on the ceiling, and, as I understand it, there are typically returns at various places along the perimeter of the room; is that consistent with your experience?
A. Returns can be both at the perimeter and other places in the room.
Q. Okay. And the idea is that the air enters the room from the diffuser on the ceiling, correct?
A. Correct.
Q. And it is directed with the intention that it eventually gets out the returns, correct?
A. Out the returns or out some other method.
Q. All right. Such as the door, for example?
A. Correct.
Q. All right. Or...I don't think there are windows in operating rooms usually, but perhaps some other exit?
A. Any other exit path that exists, yes.
Q. Okay. Are there any other exit paths besides the door and the returns, that you're aware

Page 158

of?
A. Any potential leakage in the room.
Q. Okay. But the system is designed, anyways, to go from the diffuser and wash the...to create asepsis and move particles towards the returns, correct?
MR. GOSS: Object to form.
THE DEPONENT: Yes. The air is supplied through diffusers in the ceiling. It is returned through both return grilles and also escapes through other penetrations in the operating room, as the operating room is positively pressured.

BY MS. ZIMMERMAN:
Q. Okay. And why is the air designed to come in through a diffuser and leave through the returns or the door or the leaks?
A. So that the room is under a positive pressure, and that any contaminants outside the room do not infiltrate into the room.
Q. All right. And that is, essentially, the definition of a "positively pressurized room", correct?
A. Correct.

Page 159

Q. No air is coming in through the door or other leaks, correct?
A. I wouldn't say no air, but the design is intended to prevent air to come in through those.
Q. And if it is functioning properly, there shouldn't be air coming in through a door, for example?
A. No. The opening of a door sometimes will create air currents that allow air to infiltrate into an operating room, despite being positively pressured.
Q. All right. Would you agree that, generally speaking, air under and around the operating room table is likely to be less clean than the air coming in from a diffuser?
MR. GOSS: The air coming in from or leaving a diffuser? I apologize.
MS. ZIMMERMAN: Travelling out of a diffuser.
MR. GOSS: Thank you. That is...sorry.
THE DEPONENT: Okay. So if I understand your question, the air under an operating room table is generally less clean than the air entering a supplier diffuser; is that what you asked?

Page 160

MS. ZIMMERMAN: Correct.
THE DEPONENT: I would agree.

BY MS. ZIMMERMAN:
Q. Okay. And have you, in fact, been taught that surgeons treat air underneath the operating room table as unsterile?
A. I have not heard from surgeons on their analysis of the air under the table.
Q. All right. For HVAC engineers or others that are charged with maintaining an HVAC system, would you agree that the air underneath an operating room table would be thought to be less clean?
A. To repeat my previous answer, the air underneath the operating room table would generally be less clean than the air supply through the ceiling diffusers.
MR. GOSS: Genevieve, I am not saying we need a break for lunch, but...
MS. ZIMMERMAN: But you are.

--- upon recessing at 1:42 p.m.
--- A LUNCHEON RECESS
--- upon resuming at 2:23 p.m.

Page 161

MICHAEL KEEN, resumed
CONTINUED EXAMINATION BY MS. ZIMMERMAN:
Q. Mr. Keen, we had a lunch break of about 35 minutes, and over the lunch break we were provided two copies of invoices with your name at the top; one is April 30th and one is June 2nd. And is there a third invoice as well someplace, I was thinking, that you referenced earlier in your testimony?
A. No. There was a first invoice that was paid. Those are the second and third that have not been paid.
Q. Okay. And you would expect that counsel for 3M would likely...either the Minnesota counsel for 3M or the Canadian counsel for 3M who helped retain you, one of the two of them would likely have the original invoice?
A. Yes.
Q. Okay. And the April 30th invoice is for a total of 10.5 hours, which is U.S. dollars, $2,625, and then the June 2nd invoice represents 40.5 hours of work, again at $250 per hour U.S., for a total of $10,125. Is this actually...I mean, I appreciate with the exchange rate...is this actually an increase in your hourly rate, given the exchange

Page 162

rate or change from $290 an hour Canadian to $250 American?
A. It's a slight increase to recognize the exchange rate provided by the banks in that conversion and any short-term fluctuations and any fees.
Q. And, in any event, these two invoices have not yet been paid; is that right?
A. That is correct.
Q. Okay. And perhaps these may have provided additional information about when you were provided with certain documents that we discussed in the first part of your deposition today; does that seem right?
MR. GOSS: Object to form.
THE DEPONENT: Sorry, I don't know what you are referring to.

BY MS. ZIMMERMAN:
Q. Would reference to these documents earlier in the deposition may have...would that have been helpful to you in answering questions about, for example, when you may have done any independent research versus when you perhaps read a deposition, or something to that extent?

Page 163

A. Yes, in approximate terms, that would help with the timeline determination.
Q. Okay. And then, again, these invoices that we have here are for work performed in April and May of this year; is that right?
A. Without referring to them...yes, from April to June.
Q. Okay. And are there...through June 2nd, I see that. And is there another invoice or will there be another invoice for your time in June and July in this matter?
A. Yes.
Q. Okay. Turning back to your report, go to the top of page...towards the top of page 3, your report says:
"...Proper temperature control can also directly impact bacteria growth rates..."
Do you see where it says that?
A. Yes.
Q. And then it goes on from there to say:
"...Many of these grow at a slower rate with lower temperatures..."
What is your basis for these statements?
A. In the work that I have done with the

Page 164

Canadian Standards Association or the ASHRAE, we have often talked about the evidence and rationale for standard clauses on temperature and humidity. And so, we've had a number of discussions and review of research on these topics to help in the decision-making on those clauses.
Q. And forgive me if I am not following, but I don't see where these two sentences talk about clauses at all. Instead what they say is:
"...Proper temperature control can directly impact bacteria growth rates..."
Which bacteria are you referring to?
A. It is a generic term for bacteria based on...again, you had asked about the...where I had learned this information, and that...as I had answered, in the determination of standard clauses, we have reviewed information like this as part of the committees at both ASHRAE and CSA.
Q. Okay. So would you...is there something that you can refer me to or that you rely upon in, for example, ASHRAE 170 to support these two sentences in this short paragraph?
A. Sure. The...not in support but in relation where we talked earlier about the temperature ranges, on page 2, between 18 and 23

Page 165

Celsius and 20 to 24 Celsius. The discussion of those ranges, that discussion takes into consideration the ability for bacterial growth to happen in those environments.
Q. And, at any rate, you are not a microbiologist, correct?
A. I am not a microbiologist.
Q. All right. And you don't have any training in aerobiology either, do you ?
A. I don't have training in aerobiology.
Q. And you're not going to be offering any opinions to the court in the Bair Hugger MDL case about issues touching on microbiology or aerobiology, are you?
A. I am not understanding the limitations to that question, so...I certainly speak about...in my report about different types of bacteria and microbiological particles as part of my report.
Q. Okay. And part of the purpose of both the deposition today and motion practice that will almost certainly follow as we approach trial next year, is a determination by the court about what the scope of your testimony properly may be. And, to that extent, that includes discussion and argument

Page 166

between the attorneys about what you are potentially an expert in, either by training, experience, education, that sort of thing, and, essentially, what the underlying support is for any opinion you may attempt to offer in this matter.

So, given that you are not a microbiologist and that you are not an aerobiologist, I would like to know precisely what these two sentences are...what support you claim for these two sentences.

A. Again, I have had discussions and reviewed research on this topic with the standards committees that I have worked with, with a broad representation of participants in those committees with varying types of expertise that have led me to have opinions on this matter.

Q. Okay. And there may be other people that you have spoken with that have education or training sufficient to render an opinion like this. My question is, what training or experience do you have to render these particular statements or opinions?

A. As we have already stated, I do not have specific training in microbiology.

Q. And, at any rate, there is no citation in this particular paragraph that supports

Page 167

these two sentences; is that right?

A. There is no reference noted in this report on those two sentences.

Q. Okay. By way of background, in your yellow folder, do you have references (a) and (b) in that folder with you?

A. No, I do not.

Q. No. Where are those?

A. Where are those standards?

Q. Yes.

A. I have copies of those in my office, on my computer.

Q. Multiple copies?

A. Multiple copies.

Q. Are the copies that you have highlighted or marked up in any way?

A. I have published copies that are not marked up, but I definitely have draft copies of both standards in my almost 15 years on the ASHRAE 170 and over 20 years on the CSA Z317, multiple draft copies and notes that I may have on either of those two standards.

Q. Okay. And have you provided those drafts or marked-up copies to your counsel in connection with the subpoena that was provided to

Page 168

you?

A. No, because they were not notes or drafts that were done as part of the scope of this project.

Q. But they are notes on documents that you rely upon in offering this opinion, correct?

A. They are notes related to documents that I rely upon, yes. They are not notes related to this case. And they are notes that I believe, in almost all instances, except for maybe some recent 170 were...that are even before my engagement with this case. So I did not feel that those notes were relevant to the subpoena.

Q. Okay. I am going to move on to page 4 where your report discusses air changes in an operating room. You paste in something that is noted as Figure 1. And where does Figure 1 come from?

A. Figure 1 is a reference to the numerical figure sequence of my report. The figure itself is a chart that comes from the ASHRAE design manual...design guide, sorry. It is listed here as "ASHRAE design manual". I think it is...I've got a typo in there, but it is the ASHRAE design guide that I am referring to that is in my reference listing.

Page 169

I believe it is (e). Yes, it is.

Q. Okay. So Figure 1 comes from reference number (e)?

A. And there is a note there that talks about a source where it got it from, from the CDC in 2003.

Q. All right. And I also see that there it says:

"...Note: assumes perfect mixing..."

What does that mean?

A. So that is a note that would have been in the design guide. It is not a note that I added. But the...

Q. That is your note or is that a note from the chart?

A. No, it is not my note. It is a note from the chart, and that would have come from the design guide. And I am not sure whether it's a note that is carried from CDC or not; I am not aware. My understanding of that note is that the time required for removal based on air changes again is not an exact science, because you get all kinds of different airflow currents within an operating room.

And so, this here, to give a time frame in this chart, you...the note assumes perfect mixing of

Page 170

the air and the volume of the operating room to translate the air changes into a time required, based on the air change rate per hour, at certain air change levels for removal efficiency.

Q. And you would agree that there may be areas of a room where perfect mixing does not take place?

A. I would agree with that.

Q. All right. Would you agree one of those areas may be underneath the operating room table?

A. I wouldn't...I wouldn't go to predict which areas of the operating room don't have perfect mixing, only to say that there are areas in an operating room that don't have perfect mixing.

Q. Do you know what...do you know at all what areas might not have perfect mixing?

A. No. I would defer to someone who is...who would study the fluid dynamics within the operating room for that answer.

Q. All right. Moving on to page 5, on "Surgical site infection in orthopaedic cases in the operating room". Do you understand that there is a difference between an HAI and an SSI?

A. I understand that they are different

Page 171

terms and they are not mutually exclusive.

Q. All right. What do you believe an HAI is?

A. HAI is a hospital-acquired infection.

Q. And what is an SSI?

A. It's a surgical site infection.

Q. Would you agree that a surgical site infection is a type of hospital-acquired infection?

A. Yes, I would.

Q. Do you know...I asked some questions prior to lunch about a PJI, a periprosthetic joint infection. Would you agree that a periprosthetic joint infection is a type of surgical site infection?

A. From the description you provided me earlier today, I would agree.

Q. All right. But you don't have any particular personal knowledge about...

A. A PJI, no.

Q. Okay. And your report says that all surgical operations have the potential for contamination; is that right?

A. That is correct.

Q. And you identify multiple potential sources of contamination, correct?

A. Correct.

Page 172

Q. One such potential source for contamination is equipment, correct?

A. Correct.

Q. Also instruments used, correct?

A. Yes, that is another one of them.

Q. You would also include the light handles as a potential source for contamination, correct?

A. That is correct.

Q. And then also staff apparel, including things like gloves, correct?

A. Yes.

Q. All right. And you say that: "...The main potential contamination sources are from the skin of the patient and the presence of the theatre medical staff themselves, their movements, and in general their behaviour..." What is the basis for that statement?

A. That...the basis for that comes from, again, general knowledge that I have about the sources of contamination in an operating room, and, again, from other references that I have referred to in the preparation of this report.

Q. Okay. And the next sentence then

Page 173

goes on to say:

"...It was shown that most primary arthroplasties of the hip and knee are contaminated with bacteria..."

Where was that shown?

A. I believe that is in reference to the notation that is there for the Davis paper noted in (c).

Q. So you believe that your reference (c) supports that statement as well; is that correct?

A. Yes, that is my recollection.

Q. And that is the article titled "Intraoperative bacterial contamination in operations for joint replacement", published in the Journal of Bone and Joint Surgery in 1999; is that right?

A. Yes, that is correct.

Q. All right. And this is one of the articles that you weren't sure whether you had prior to being retained by the 3M Company in this matter, correct?

A. No. This is one of them; unsure whether I found it on my own or whether it was provided by 3M counsel, but both within that time frame of being retained.

Q. Okay. And I am sorry if I misspoke.

Page 174

That was...I think that we are on the same page. You weren't sure one way or the other whether that may have come from 3M or you independently found that?
A. Correct.
Q. Okay. In any event, it's an article that has...would you agree that it's an article that you have recently come into possession of, either through your own independent research or by being provided by counsel?
A. Within the last six months, yes.
Q. Okay. This isn't something that you had reviewed prior to your involvement in this matter?
A. Correct.
Q. Do you know if you have other articles that touch on the likelihood of explaining contamination in arthroplasties of the hip and the knee?
A. Yes. There are other articles that speak to this, the areas of contamination in the operating room and...as potential sources for infection.
Q. Other articles that you found?
A. Other articles that either I found or provided by 3M counsel.

Page 175

Q. Okay. And those articles are cited again in the reference listing beginning on page 23?
A. Yes, that is correct.
Q. All right. In the fourth paragraph on that page 5, you say that:
"...It is generally agreed that 80 to 90 percent of HAIs are transmitted by direct contact..."
You understand that that is not the same as surgical site infection, correct?
A. I understand. In this case, it is referring to overall hospital-acquired infections, and it is not specifically referring to surgical site infection.
Q. Okay. And so you would agree that this sentence, to the extent that it is talking about HAIs, you are not offering an opinion that 80 to 90 percent of surgical site infections are transmitted by direct contact, correct?
A. That is not what it says, correct.
Q. And you're not going to be offering that opinion at some point in this...
MR. GOSS: Object to form.
MS. ZIMMERMAN: Basis?
MR. GOSS: Well, I am not sure what

Page 176

opinions...I mean, I would leave it to him to say whatever opinions he is raising, though.
MS. ZIMMERMAN: Well, in the report, it's specifically hospital-acquired infections.
MR. GOSS: M'hmm.
MS. ZIMMERMAN: If he is modifying or changing his report today, as we sit here, the plaintiffs are certainly entitled to know that...
MR. GOSS: Sure.
MS. ZIMMERMAN: ...and to understand what the basis is of that, so...
MR. GOSS: I don't disagree.
THE DEPONENT: So this sentence deals with HAIs, I would agree. And I speak in other areas in my report about the risks of surgical site infections, although I...they are not stated in terms of these same percentages, if that is what you're asking.

BY MS. ZIMMERMAN:
Q. Okay. So you would agree that, whatever these percentages are that your report links to HAIs, that you have not cited evidence about the

Page 177

percentage of SSIs transmitted by direct contact?
A. I do not believe I have cited a number in the same form, but I have spoken to the risk.
Q. All right. And, at any rate, you don't have support for contention that 80 to 90 percent of SSIs are transmitted by direct contact, correct?
A. I do not recall if I have seen in the reference documents that I have looked at a specific number that I am relying upon, and I do not believe it is quoted in my report or by my report right now, but I have reviewed, in certainly general terms, the risks, levels of surgical site infections, as part of the referencing for my report.
Q. Okay. Well, and you understand from the beginning of our discussion here today that I am here on behalf of, you know, just about, probably by the end of this summer, 3,000 people that have made claims that the Bair Hugger has caused surgical site infections and that they have had all manner of medical procedures, including amputation and death, as a result.
This today is their one chance, by my questions, to ask what the basis is of your opinions

and what you intend to offer at court in support of that. So my question to you is, you have now listed out in your report in writing that you believe 80 to 90 percent of HAIs are transmitted by direct contact. You would agree that your report, at least on this page, does not suggest or state that 80 to 90 percent of SSIs are transmitted by direct contact, correct?

A. I would agree that my report does not state that there.

Q. All right. And you understand that you are required to outline the opinions that you intend to offer in this matter and the basis that supports those opinions, correct?

MR. GOSS: Object to form that he wouldn't have any reason to know what the legal requirements are. If you understand, you can answer.

THE DEPONENT: I don't understand all the legal requirements, as you asked.

BY MS. ZIMMERMAN:

Q. All right. And the reason that you prepare a report in a case like this is so that I can understand what your opinions are and I can test the edges of that to figure out if I think that they are

based in fact or in reasonable science or in good engineering practice, so that we can determine whether they are reliable, okay?

A. Okay.

Q. All right. And that is the purpose for preparing a report and that is the purpose for the deposition today, to understand what it is that is the underlying support for the opinions you intend to offer in this case, all right?

A. Okay.

Q. And so what we are entitled to do today is to examine the full scope of what it is you intend to testify to, which means you don't get to come back next week or next month or on February 26th and change the numbers that you have offered in your expert report. You understand that?

A. I understand it, as you have just told me.

Q. Okay. And, at any rate, with respect to the transmission of pathogens and particularly with respect to bacteria, you would rely on a microbiologist to quantify the risk to patients, correct?

A. I would, yes.

Q. All right. Your report goes on to

say:

"...Transmission of airborne hazards is influenced by factors beyond the control of the engineer that include movement of patients, undiagnosed patients, visitors, concentration of patients, and patient susceptibility..."

Is it your understanding that that is an exhaustive list of factors that may influence transmission of airborne hazards?

A. No.

Q. All right.

A. No, I would not say that is an exhaustive list.

Q. Okay. Now, this section 5 at the bottom of page 5, you say "Bair Hugger potential for risks of contributing to surgical site infections", and this is...this section is a little confusing to me, in all candour. It says that your report is reviewing the following areas of potential risk, and that is: airborne bacteria passing through the unit and through the filter, and then also, disruption of airflow that could increase risk of particles settling in the surgical site. Is it your testimony today that that is the focus of the questions or the

risks that you are to address?

A. No. This section was really an introductory statement to reflect upon the scope that was coming in the later parts of the report, and, as mentioned previously, was not completely inclusive of everything I have talked about in the report.

Q. All right. Well, I understand it's not a complete recitation of what is in the report, but it is kind of three sentence fragments just in the middle of a report, and it doesn't seem to actually identify a specific opinion. Does this reflect the problem presented to you, or the scope of work that you were asked to address?

A. Again, it serves as a linking introductory statement of what is to follow in the report on the scope, and, as mentioned previously, probably omits some pieces of it, and is not completely and all inclusive of what is to follow in the report.

Q. Okay. And, at any rate, would you agree that there is nothing specific in this number 5 that is an opinion?

A. I would agree that there is nothing specific that is an opinion in that number 5.

Q. All right. Turning to page 6,

Page 182

"Filtration in the Bair Hugger", you say that the Bair Hugger does, in fact, contain a filter, and you say that:

"...The incorporation of a filter is noteworthy because to [your] knowledge, there is no ASHRAE or industry requirement to use filters in fan-blowing OR equipment..."

You are a trained engineer, right?

A. I am.

Q. All right. Are you aware of a single motor that doesn't require a filter?

MR. GOSS: Object to form.

THE DEPONENT: Yes. I am aware of other pieces of equipment in an operating room that do not have a filter that have a fan-driven...a fan blowing.

BY MS. ZIMMERMAN:

Q. Okay. Which other motors don't have filters?

A. As an example, microprocessor equipment that has a cooling fan on it does not contain a filter in many instances.

Q. Okay. So is it your testimony then

Page 183

that the incorporation of the filter on the Bair Hugger is unnecessary?

A. No, that is not my testimony. My opinion in this matter is that I am not aware of requirements to use filters in fan-blowing equipment that reside in the OR, and that I have observed that the Bair Hugger has a filter.

Q. Okay. Have you observed any other forced air warming blankets or products in an operating room?

A. No, not specifically, unless I inadvertently saw one prior to this case. But, no, I have not specifically seen, certainly not since engaged in this case, any other forced air warming equipment.

Q. All right. Are you aware, through your own research or through conversations with colleagues or any other way, that other forced air warming products, in fact, use a HEPA filter?

A. I am aware of other forced air warming equipment that is out there, but I am not familiar with the filtration components of those other forced air warming...other forced air warming pieces of equipment.

Q. Okay. And you know from the e-mail

Page 184

with the hospital infection prevention...

A. Are you referring to my e-mail correspondence...

Q. Catherine Hogan.

A. Yes, with the director of perioperative services.

Q. Yes. Okay. And you know from that e-mail that the hospital that you work with uses both forced air warming and also warm blankets; is that right?

A. From her correspondence, yes.

Q. Okay. So you're aware that there are multiple potential modalities for warming patients during an operation; is that right?

A. Yes, I am aware of that.

Q. Okay. And I think you said before that you do not consider yourself an expert on filtration; is that right?

MR. GOSS: Object to form.

THE DEPONENT: I have experience in working with filters in hospital applications.

BY MS. ZIMMERMAN:

Q. All right. Have you ever designed a

Page 185

filter?

A. I have never designed a filter.

Q. Are you familiar with different filter media?

A. I am aware of different filter media.

Q. Do you know what the impact is of different filter configuration, filter efficiency?

A. I don't understand your question.

Q. Okay. So, for example, on page 6 you have two...you have a Figure 2 and a Figure 3. One shows a cylindrical filter for the Bair Hugger 505, and then Figure 3 shows a rectangular filter for the Bair Hugger 700 series. As you sit here today, do you know if the shape of the filter would impact in any way the efficiency of the filter?

A. I have not done any review as to whether the shape of the filter has any impact on its efficiency.

Q. All right. And that is not something that you have education or training on, at least as you sit here today?

MR. GOSS: On the shape of the filter?

MS. ZIMMERMAN: Yes.

THE DEPONENT: I mean, filtration was one of the topics that would be part of my

education and training as an engineer, but as to specific shape experience of filters and any detailed calculation on shape of filters, no, I do not have experience on that.

BY MS. ZIMMERMAN:

Q. Okay. Would it be fair to say that your experience with filters, certainly professionally in the hospital setting, is really focused on identifying the applicable standard in ASHRAE or the Canadian standard and finding a filter that is advertised to meet the requisite MERV standard?

A. In my work in the hospital, my role would be in following the appropriate standard and applying the right application of filter to that. Certainly in my role on standard committees, we have examined the evidence and discussion amongst the committee of the different performances of different filters.

Q. Has your committee examined the filters involved with Bair Hugger at all?

A. No, they have not.

Q. Has your committee discussed Bair

Hugger in any capacity?

A. Yes. There was, interestingly enough, a reference to the use of a Bair Hugger in a research project that was shared with the committee at the meetings just a few weeks ago, and how it was a component of the setup of a project.

Q. All right. And what was your committee's involvement with that?

A. This was a presentation by the research group to the committee of the topic of that research. The focus was not on the Bair Hugger itself. The Bair Hugger was a component that was used in the research. And so we received a presentation from this group and for consideration for the committee's use in applying to a standard.

Q. And who presented?

A. I don't recall right now.

Q. Does Gormley ring a bell?

A. Gormley was one of the names, but he did not present. It was one of the names in one of the research...we heard from a number of research projects, and that is why I can't remember right now.

Q. Moving on to, I think it is part b) of section 6, which is on page 7. Your report talks about...there is a section that is titled "Bair

Hugger filters are tested to ASHRAE 52.2 MERV rating". Do you see that?

A. Page 7, section b), "Bair Hugger filters are tested to ASHRAE 52.2 MERV rating", yes, I see that.

Q. Okay. And this Figure 4, the MERV parameters, your citation there is to the letter (g); is that right?

A. Yes.

Q. And that is "Understanding MERV - NAFA User's Guide for ANSI/ASHRAE Standard 52.2", published in 2012. This is a document that you obtained through your own independent research; is that right?

A. Just...2014, but, yes, that is one of the ones I found in my own search.

Q. Okay. But you saw this for the first time in connection with doing the research in the Bair Hugger matter; is that fair?

A. This document?

Q. Do I have that incorrect?

A. Is that what you are asking, the first time I saw this document?

Q. Yes.

A. Yes, that is correct.

Q. Okay. Were you familiar with a chart like this in other ASHRAE standards that you have seen in the past few years?

A. Yes, I was.

Q. Okay. So the Figure 4 itself is not something new to you; is that right?

A. That is correct.

Q. And this is a standard published in ASHRAE, 52.2, certainly something you find reliable, correct?

A. Yes.

Q. All right. And the summary of the text that you have...or, basically, all of page 7, are you citing all to (f) and (g) for all of these propositions?

A. I'm sorry, can you repeat that?

Q. Yes. So, on page 7...

A. Yes.

Q. ...there is a citation or an endnote to article letter (f), as in "Frank"...

A. Yes.

Q. ...which is the ASHRAE Standard 52.2, and then the Figure 4 is endnote (g).

A. Yes.

Q. Those are the two citations that are

Page 190

provided on page 7.
A. Yes, they are.
Q. Are there any other citations that support the notions that you offer on page 7?
A. There are no other reference citations on page 7, other than (f) and (g).
Q. And would you characterize any of the statements on page 7 as your opinions?
A. The first paragraph, I am not sure whether that one was from my own opinion or whether that was from any of the references, but I would share the opinion in the first paragraph.
Q. And I guess the question that I was trying to pose here is, you characterize these as opinions that you are offering, or are these, you know, facts that you're citing to from ASHRAE or generally accepted standards?
A. Again, as I said, the table itself is referencing a standard that exists. What is detailed in the first paragraph could be shared as one of my opinions. The remaining paragraphs really refer to the standard.
Q. And you say:
"...Filtration in an operating room environment may protect against the

Page 191

intrusion and spread of airborne pathogens..."
Correct?
A. Correct.
Q. All right. And that is just from your basic general experience, education, training?
A. Again, I don't recall whether this one was actually cited or whether it would be my opinion, but I definitely would share that, based on my experience.
Q. Moving on to page 8, you have... subsection c) here is on the "Bair Hugger filter tests". And you cite to three separate testing... test results. Is this the sum universe of the tests that you have been provided with respect to the Bair Hugger filters?
A. No.
Q. What other testing have you been provided with respect to the Bair Hugger filters?
A. There was at least one other test that I received, and I don't recall the name of it, but it was an incomplete test that I could not rely on to make an opinion as to the MERV rating of the filter from the test, so I did not include it.
Q. All right. And you don't know what

Page 192

test that was or who did it?
A. I don't recall at this time.
Q. Would you agree that all three of the filter tests that you cite to on page 8 were done in the year 2016?
A. Yes.
Q. Do you have any information, as you sit here right now, about when the filters that were tested were manufactured?
A. No.
Q. Do you have any information, as you sit here today, about where those filters may have been stored?
A. No.
Q. Do you have any information about the condition of the filters that were tested in 2016?
A. No.
Q. The first test that you cite to is the LMS Technologies lot 4670185, which says, according to your report, is the test of a Bair Hugger model 505 filter, and the test was done on April 26th, 2016; is that right?
A. April 28th of 2016.
Q. I am sorry, April 28th of 2016. Is it your understanding that the Bair Hugger model 505

Page 193

is still in use?
A. I don't know if the Bair Hugger 505 is still in use.
Q. All right. And, as you sit here today, you don't know if the Bair Hugger model 505 filters are continuing to be manufactured?
A. I do not.
Q. Similarly, with respect to the second test that you cite to, the LMS Technologies lot 4640927, that is testing done April 28th, 2016, on a filter for a Bair Hugger model 750. Do you have any knowledge, as you sit here today, about whether the Bair Hugger model 750 is still in use in the medical field?
A. I do not.
Q. Do you have any knowledge, as you sit here today, about whether or not the filter is continued...is still being manufactured?
A. No, I am not certain as to whether that filter is still being manufactured.
Q. All right. And with respect to both the first two tests, on the filter for the model 505 and the filter for the model 750, you have no idea what date those filters were manufactured; that is correct?

A. That is correct.
Q. All right. Are you aware that the filter media for the 505 was changed at one point?
A. No, I am not aware of that.
Q. All right. Are you aware of any changes that may have been made to the Bair Hugger filter media?
A. I know of two different filter types that are shown here in the tests and are shown in my...other place in my report, but, other than that, I am not aware of any other changes to the filter.
Q. Okay. And that is the cylindrical design versus the rectangular design we talked about?
A. That is correct.
Q. All right. Are you aware of what media is used in the Bair Hugger filters?
A. Only as described in these tests.
Q. All right. And these tests describe it as a, at least...well, in your report, I don't think that it described the media at all, does it?
A. It describes it as a white mini-pleated filter.
Q. Okay. But the actual media itself, it doesn't say what it is made out of, correct?
A. No, it does not.

Q. All right. And you would agree that what the filter media is made of may well be relevant to filtration efficiency questions, correct?
A. Yes.
Q. And you would agree that the length of time between manufacture and this test in April of 2016 could also be relevant to testing of the filter, correct?
A. I don't know if that is relevant.
Q. Well, if, for example, the filter was kept in a damp, underground facility, and it was unwrapped and not protected from the elements, and it sat there for seven, eight years, would that have an impact on testing on filtration?
MR. GOSS: Objection, improper hypothetical, calls for speculation.
MS. ZIMMERMAN: You can answer.
THE DEPONENT: My understanding is that the filter was tested on April 28th, 2016 in the first two instances that you have mentioned, and that that test was on that date. And so, the test did not relate to what happened before that date.

BY MS. ZIMMERMAN:

Q. Okay. But, as you sit here right now, you don't have any idea about how...when the filters that were tested were manufactured, correct?
A. I do not know when they were manufactured.
Q. And you don't know by whom they were manufactured, do you?
A. I do not know by whom they were manufactured.
Q. And you don't have any idea, as you sit here today, about what conditions those filters were kept in, correct?
A. Correct.
Q. All right. And do you have any idea, as you sit here today, whether they are, in fact, identical to any filters that would have been manufactured and used in these devices; for example, when the 505 was actually still in use?
A. It is described in the report as a filter from a 505, so I would take from that report that it is a filter from a 505.
Q. Okay. And if the 505 filter has not been manufactured for five years, is it your understanding that the filter is then a newly manufactured filter, or one that has been sitting on

the shelf, or does it matter?
A. I have no comment on...
MR. GOSS: Hold on, objection to form, improper hypothetical. You can go ahead.
THE DEPONENT: I have no comment on the manufacture date of the filter.

BY MS. ZIMMERMAN:
Q. All right. Do you think the manufacture date of the filter impacts the filtration efficiency?
A. No.
Q. Do you think the manufacture date impacts the conclusions that you can draw about the 505 filters more broadly?
A. Could you repeat that question, please?
Q. I can sure try. Do you think that the date that the filter itself was manufactured impacts conclusions you can draw about, for example, the 505 filters, historically speaking?
A. I would need to look at that context.
Q. What is your understanding of the life of a filter?
A. Can you give me some more context to

that question? It is quite vague for me...
Q. So, do you understand that the Bair Hugger filter, for example, is to be changed every 500 hours?
A. I am not aware of that specific requirement, but I can understand that there might be a requirement for changing, yes.
Q. Okay. And do you think knowing the life of a filter is important to rendering opinions about filtration?
A. In general terms, I would say yes.
Q. Okay. And do you know how to determine when a filter ought to be replaced?
A. Yes.
Q. How?
A. There are a number of different ways by which we determine a filter to be replaced. One is by measure of the pressure differential across that filter, another is by visual inspection.
Q. And is this something that you do?
A. I don't personally change the filters, but I have examined filters for the need to change them.
Q. Okay.
A. And just to finish my answer on that

one...I haven't finished yet...the time is also a factor that we use in the changing of filters.
Q. And what is your understanding of what role time plays in the changing of filters?
A. I have used time as a general guide that is easy to apply for the changing of filters.
Q. Is that your standard or is that an industry standard?
A. I would say it's a common standard that is used across the industry, and it is certainly one that I have used.
Q. The pressure testing of a filter that you reference, is that a testing that you have personally conducted?
A. It is...when you say a testing I have conducted, we have instrumentation across filter banks that gives you a reading of that pressure differential. And, yes, I have read that pressure differential across the filter banks personally.
Q. And when you are reading the pressure differential numbers, I assume...
A. Yes.
Q. ...is that something that is readily visible from the...outside the filter bank?
A. If you have that instrumentation. So

I have worked with air handling units, for example, that have instrumentation outside the air handling unit that read the differential across a filter.
Q. All right. Does it work kind of like a household vacuum cleaner, where, you know, if your vacuum bag is full and needs to be changed, a red light comes on?
A. That is an interesting analogy and...but I would say, in general terms, that is similar, yes.
Q. All right. And are you aware, actually, that some of the newer prototypes for Bair Hugger include, in fact, a light that comes on when the filter needs to be changed?
A. No, I am not aware of that.
Q. All right. Are you aware that the 775 doesn't have a light to indicate when a filter ought to be changed?
A. I am not aware of that.
Q. Okay. The third test that you reference on page 8 has to do with the test on August of 2016 of Bair Hugger model 775. Do you know, as you sit here right now, whether the 775 is what you saw?
A. It might be but I don't know for

sure.
Q. Okay. And do you have any idea, as you're sitting here, why that test was done several months after the tests in April of 2016?
A. I do not know why the time difference in that one.
Q. Have you been produced or provided with any copies of any tests on filtration done prior to 2016?
A. So the fourth test that I mentioned to you that was inconclusive, I don't know what the date of that test was.
Q. Okay. Would you expect that there would be tests on filters done throughout the course of the life cycle of the Bair Hugger products?
A. I would only be guessing, so, no, I wouldn't presume that.
Q. Okay. As an engineer, were you taught that it was important to test the products that you would develop or market or use?
MR. GOSS: Objection, vague.
THE DEPONENT: Yes. I didn't develop products.

BY MS. ZIMMERMAN:

Q. Okay. You have never developed products?
A. I have not developed a product.
Q. Okay. And, at any rate, as you sit here right now, you're not aware of any testing from the year 2000, for example, with respect to filtration of the Bair Huggers, correct?
A. I am not aware of any testing from the year 2000 on the filtration of Bair Hugger.
Q. And have you been provided any testing about the filters on Bair Huggers from 2005?
A. Again, the fourth one, I couldn't tell you what date it was, but that is the only other test that I have been provided.
Q. Okay. And so, as you sit here today, there could have been dozens of tests about the filter or zero tests about the filter in...aside from the one undated test you have referenced, you're just not aware of that; is that fair?
MR. GOSS: Object to form, calls for speculation.
THE DEPONENT: I am aware of the four tests that were presented to me, and I am not aware of any others.

BY MS. ZIMMERMAN:
Q. And you relied on counsel for 3M to provide whatever information you may need with respect to filter testing in this case, right?
A. That is correct.
Q. Okay. Are you aware of any evidence or have you been provided any documents that speak to the life of a filter for a Bair Hugger?
A. No.
Q. And you don't personally have any experience with how a manufacturer determines the life of a filter, do you?
A. I don't have the personal experience in how a manufacturer determines the life of a filter.
Q. Do you think it would be in good practice to have a light on a device indicating that the filter should be changed?
A. I don't know what the practices would be for changing the filter on a Bair Hugger in operation.
Q. And that is not something you have ever been asked to do, is to change the filter?
A. I have never been asked to change the filter on a Bair Hugger.

Q. All right. Have you talked with anybody who has?
A. No, I have not.
Q. Do you know who at your hospital is responsible for that, if it's someone at your hospital?
A. I don't know specifically who.
Q. You know, actually, what is your understanding of your hospital's relationship with 3M?
MR. GOSS: With respect to the Bair Hugger?
MS. ZIMMERMAN: No.
THE DEPONENT: Can you give me some more understanding of that question?

BY MS. ZIMMERMAN:
Q. How many...
A. What do you mean by "relationship with 3M"?
Q. How many 3M products does your hospital buy every year?
A. I don't know the number of total products they buy from 3M.
Q. A lot?

A. I don't know the total number.
Q. Okay.
A. I do know they purchase at least a few, but I don't know how many.
Q. All right. Who would know that information?
A. I would imagine that our procurement department would be more aware of that information.
Q. And have you discussed your testimony or retention in this case with anybody at the hospital?
A. Yes, I have.
Q. All right. And they are aware that you have been retained by 3M?
A. Yes.
Q. And did they see a problem with that in any way?
A. No.
Q. Have they, in fact, encouraged you to do that?
A. No, I wouldn't use the word "encouraged", but they have supported the fact...I presented it and they have supported the fact that I am doing that.
Q. Okay. And, as you sit here today,

Page 206

you don't have any idea of what financial relationship of any kind might be...there might be between your hospital and 3M?

A. No, I am not aware of the financial relationship.

Q. Do you know if there are any clinical trials or other research that is presently ongoing at your hospital?

A. There are clinical trials of research happening at the hospital, yes.

Q. All right. Is 3M sponsoring any of them?

A. I have no idea whether they are or not.

Q. All right. Would the procurement office know about that as well?

A. Not necessarily.

Q. Has 3M sponsored any of the work that you have done?

A. No, they have not.

Q. What other devices or pieces of equipment in an operating room are you aware of that blow air?

A. So, as I had mentioned previously, other microprocessor equipment has fans on it that

Page 207

blow air.

Q. Anything else that blows air in the OR?

A. Anaesthetic gas machines.

Q. Anything else?

A. To a sort of opposite side of things, it's kind of like blowing air, but, essentially, scavenging and suction...suck air, right, effectively, which is a negative form of blowing air.

Q. Any other items inside an operating room that you're aware of that blow air?

A. Not specifically.

Q. Beginning on page 9, you have a section starting at number 7 regarding the "Alleged impacts of Bair Hugger on airflow in an operating room", and you talk about laminar airflow in operating rooms at sub a). What is your experience with laminar airflow in operating rooms?

A. My experience has to do with the design of operating rooms and the consideration of such design during standard committees.

Q. And you talk about...or you reference Group E...well, it says:

"...The standard for operating room ventilation is to provide air supply systems

Page 208

based on laminar flow diffuser arrays..."

And then it says "(Group E)". Are you referring back to Figure 5 on page 8?

A. No.

Q. What are you referring to?

A. I am referring to the table of diffuser types that are listed in the standards.

Q. And where do you find that?

A. In ASHRAE 170 or in CSA Z317.2. Those tables would be in either one of those.

Q. Okay. And so, when you say Group E, you are specifically referencing something but there is no endnote there?

A. Yes. I am speaking in that sense from my knowledge and experience, but if...it comes from the standard table, that is correct.

Q. Okay. Did the operating rooms in your hospital have laminar airflow?

A. The hospital...the systems in the hospital have diffusers that are set up to provide that laminar airflow. As I say in my report, achieving pure laminar airflow is a very difficult thing to actually achieve in practice.

Q. Okay. But is it fair to say that sometimes people say laminar airflow and it may not

Page 209

be truly laminar from a physics perspective?

A. Correct.

Q. Okay. I don't know if you do it here in Canada, but we call things Kleenex or Band-Aids that may not be brand-named Kleenex or Band-Aids. Is it about the same kind of thing?

A. No, it is not the same kind of thing.

Q. Okay. What is it?

A. In this here, as you can see in my report, I speak of laminar airflow based on a design intent. That design intent, as you can see in here, often could potentially, theoretically, hold true in an empty operating room, but in the actual operation of the operating room with all of its people and equipment and functions, that laminar airflow is often disrupted, and so is not purely achieved. But the design of the system is set up to attempt to provide a laminar airflow through the selection of the design of the operating room supply system.

Q. So is it your testimony that laminar airflow could be achieved in an operating room if the diffusers were universally applied across the entire ceiling and there were no people or other equipment in the room?

A. Theoretically, yes.

Q. All right. And does true laminar airflow ever exist?
MR. GOSS: In an operating room?
THE DEPONENT: In a functioning operating room, yes?
MS. ZIMMERMAN: Yes.
THE DEPONENT: I would say it does not ever truly exist in a functioning operating room, and when it is referred to as its use in operating rooms, it is often the design intent to provide a laminar airflow and not the actual achievement of the laminar airflow.

BY MS. ZIMMERMAN:
Q. Do you know, is the laminar or the attempt to provide laminar airflow in operating rooms in Canada equivalent to the attempt to provide laminar airflow in operating rooms in the United States, or is it more akin to the United Kingdom?
A. I...to the best of my recollection, I believe it is almost...if not identical, it is...I believe it is the same as between ASHRAE 170 and CSA Z317.
Q. Do you personally have experience

calculating whether airflow is truly laminar?
A. No, I do not.
Q. Do you have any experience...well, do you know what a Reynolds number is?
A. Yes, I do.
Q. All right. Do you have experience or ability to calculate a Reynolds number?
A. I have done that, yes.
Q. All right. In connection with operating rooms?
A. No, not in connection with operating rooms.
Q. Okay. When have you had occasion to use a Reynolds number?
A. During my studies in mechanical engineering.
Q. Okay. Have you done any work in calculating or doing Reynolds number calculations in the past 20 years?
A. No, I haven't.
Q. Okay. So, as you talk about the laminar airflow in section 7 of your report, you have citations to a couple of different journal articles. The first, you say:
"...Laminar airflow has generally been

associated with decreased air microbial contamination in clean surgery..."
And you cite to an article titled "Air contamination for predicting wound contamination in clean surgery: A large multicenter study". It says 2015, but I am not sure that I can see where it was published, I apologize. It looks like it is endnote (I).
A. Correct. And I believe that was published in the American Journal of Infection Control.
Q. Okay. And, generally, you find the American Journal of Infection Control to be a reliable source?
A. I have no comment on whether it is reliable or not.
Q. You don't have an opinion, as you sit here, about whether it is reliable or authoritative?
A. The journal itself?
Q. Yes.
A. It's a source of information and I don't have any predisposition about whether it's reliable or not.
Q. Is it something that you subscribe to?
A. No.

Q. Is it something that you have found reliable from time to time?
A. I have found documents from within the journal that I have used for reference and relied upon.
Q. At least this one is reliable because you refer to it, right?
A. Again, I haven't done a full dissection or critique of the journal, but have relied on some of the information within it.
Q. Okay. Is it a peer-reviewed journal, to your knowledge?
A. I don't recall.
Q. Would that be relevant to you?
A. That is information that is interesting to know, but would...whether it's peer-reviewed or not doesn't change that it might contain relevant information.
Q. Well, you would agree, particularly these days, it's important to double-check sources and make sure that people have reliable...both sources and methods for fact-checking, for example?
A. What is the context for "important"?
Q. Compelling, trustworthy, reliable.
A. No. I believe that an article could

Page 214

be reliable, whether it's peer-reviewed or not.
Q. Okay. And is it your testimony then that articles in the American Journal of Infection Control are reliable if they are on your list of references?
MR. GOSS: Object to form.
THE DEPONENT: Again, I haven't critiqued the rigour of the research done in all of these papers, and have read through them and then rendered opinions based on what I have read.

BY MS. ZIMMERMAN:
Q. And, in any event, this particular article from the American Journal of Infection Control is one where you are not sure if you found it on your own or it was potentially provided by counsel, correct?
A. Correct.
Q. The second sentence in that paragraph, you cite article at endnote (j), which was provided by counsel. It is an article titled "Airborne bacterial contamination during orthopaedic surgery: A randomized controlled pilot trial", published in the Journal of Clinical Anesthesia in

Page 215

2017. Do you see that?
A. Yes.
Q. And do you know if that is a peer-reviewed journal?
A. I don't recall.
Q. All right. And is that relevant to you in evaluating the publication?
A. Whether it's peer-reviewed is potentially relevant, but I would, again, say that the...whether it is peer-reviewed or not, it was a source of information that I reviewed, and then made an opinion based on the information I read.
Q. All right. And, at any rate, you cite this article in the Journal of Clinical Anesthesia for the proposition that...it says:
"...absence of a turbulent-free laminar airflow resulted in significantly increased bacterial counts..."
So am I correct in understanding you to say laminar airflow is therefore associated with decreased bacterial counts?
A. This statement is saying that not having laminar airflow increased bacterial counts. It is not saying the inverse.
Q. Okay.

Page 216

MR. GOSS: Genevieve, whenever you're ready for a break.
MS. ZIMMERMAN: Yes, in a little bit.

BY MS. ZIMMERMAN:
Q. So the Figure 6 that you have at the top of page 10, what is the source for that? I mean, it says (k), so we are back to the...this is Price Industries; is that right?
A. Correct.
Q. All right. And is that...I think you said earlier that is not a peer-reviewed publication, correct?
A. That is correct.
Q. That is some sort of a guide put forth by some sort of corporation; is that right?
A. That is correct.
Q. And, in any event, Figure 6 does not represent your experience, anyways, with respect to operating rooms because the diffusers go all the way across the ceiling; is that right?
A. In Figure 6, it does not represent the practical application that I have seen, no.
Q. Okay. And you included it in your report to...as demonstrative of how things are...why

Page 217

did you put it in your report if it's not the way things are done?
A. I included it in my report as a depiction of the idea of the ideological sort of laminar airflow of an empty room with a full array across the room, in comparison to what is practically done, which is described later in that section.
Q. Okay. And then you talk in this section about airflow velocity and the intent to prevent the possibility of surgical zone contamination due to entrainment of the recirculating room air. Do you see where I am reading from on that?
A. Yes.
Q. All right. And that is one of the goals that you had when you were more primarily responsible for the HVAC systems, and now as you supervise people who have that responsibility, correct?
A. That would be the goal of that section, is to prevent that re-entrainment in that intended laminar airflow field.
Q. All right. And you did read Dan Koenigshofer's report, correct?
A. Yes, I did.

Page 218

Q. And I think that he described the intent of the HVAC system is to clear a mythical fly from the room. Have you heard that analogy presented before?

A. No, I don't recall that analogy, actually.

Q. Okay. Well, I think that he talks about, if there was a fly in the room, that the idea would be this airflow coming out of the diffuser would get rid of the fly. But if it doesn't make sense, it doesn't make sense. But that is the goal, at any rate, of these laminar diffusers, is to prevent the possibility of surgical zone contamination, right?

A. Correct.

Q. Okay. And when you say surgical zone, that would certainly include the operating room table, correct? Let me ask it differently, what do you believe it includes?

A. Yes, I would. I mean, when you asked that question, there are two ways of looking at surgical zone. There is actually the surgical site itself and the immediate area...

Q. The incision site?

A. ...the immediate area around the

Page 219

incision site, and then there is what is typically known in the HVAC is the surgical zone, which is the space that is sort of 12 inches around the surgical table. So it depends on the context of that definition.

Q. Okay. And as you have worked in practice, the intent is to clear as many potential contaminants from that entire zone extending 12 inches beyond the surgical table, correct?

A. Not only to clear but to prevent re-entrainment.

Q. Okay. And that is really the reason that you have this unidirectional airflow, correct?

A. Primarily to prevent the entry of other airstreams, yes.

Q. Okay. And when you talk about re-entrainment, is that what you're depicting with the arrows that kind of go back up?

A. No.

Q. No. What are those arrows intended to depict, or do you know, if they are not your drawings?

A. They are not my arrows, and I was not depending on those for the description that I was using the diagram for.

Page 220

Q. Okay. And have you seen any of the other schematics or drawings done by other experts disclosed by either the plaintiffs or the defendants in this case with respect to airflow trajectories or particle movement?

A. Yes, I have.

Q. What have you seen?

A. I can't recall exactly all that I have seen, but...at this stage.

Q. Okay.

A. Unless you had something specific that you wanted to point out, but I have seen some, that is for sure.

Q. Okay. Do you know if they have been in colour?

A. I have seen some in colour, yes.

Q. And they were represented to you visually, I assume?

A. Yes.

Q. Have you seen videos?

A. Yes.

Q. All right. Have you seen digital animations or computer-rendered animations?

A. At least pictures, if not video of computer animations.

Page 221

Q. All right. And do you know if those are...do you know if those were only from Settles?

A. I believe there would be more than just Settles.

Q. Do you know if you may have seen some of the videos that have accompanied Professor Abraham's report?

A. I don't know, and I don't recall Professor Abraham's name in connection with any of these.

Q. Do you know if you have seen any of the reports...or, pardon me, the videos that were generated in connection with Said Elghobashi's report?

A. I can't recall if any of the videos I saw were associated with Elghobashi.

Q. What do the videos look like? Were the people in them?

A. Yes, some of them had people in them.

Q. Real people or animated people or...

A. No. I remember some with real people in them.

Q. Okay. And when were you provided these?

A. Over the course of the past five

Page 222

months.
Q. Okay. Are any of them...were you... were any of them provided to you very recently?
A. No. This would be prior to the completion of my report.
Q. Okay. And did you rely upon those animations in reaching your opinions?
A. I would say that those videos were a component of what led to my final opinions.
Q. And are they reflected in the list of references in your report?
A. No, they are not.
Q. Why not?
A. Again, I don't...some of these videos I have seen but do not have official copies to be able to provide a reference to.
Q. All right. And where have you seen the videos, online?
A. Some of them have been online, yes.
Q. Were they provided to you by Dropbox or an FTP site or...where did you find them?
A. I think...I can't recall, to be honest.
Q. Okay. But you viewed these videos at some point as you were drafting your report and

Page 223

relied on them in some way in reaching your ultimate opinions?
A. That is correct.
Q. All right. But they are not listed in the reference materials?
A. That is correct.
Q. Okay. And do you know, as you sit here right now, whether they were online publicly available or...
A. I know that for sure some of them were on YouTube and publicly available.
Q. Okay. There is a lot of stuff on YouTube, and I suspect that none of us rely on everything we see on YouTube. But the purpose of this deposition is to figure out what you have relied upon in reaching the opinions that you are prepared to offer in this case, and I am struggling because I don't...you know, I see a reference to Settles' report. But, to the extent that you are directed to or discovering videos on YouTube and relying on those in reaching your opinions, they are not disclosed here, and that makes the opportunity to investigate your reliance on those very difficult. What was it about the videos that you relied on?
A. I think, in general, the videos were

Page 224

an animated depiction of what were described in some of the reports that I referenced. And so, again, they provided just additional dynamic visual context to support my research in coming up with opinions.
Q. So the videos supported your research. So, looking again at the references that you have listed...it is not an ASHRAE video, I trust; is that correct?
A. I do not believe there are any ASHRAE videos in what I saw.
Q. And there is no CSA standard video that you are relying upon, I assume?
A. No.
Q. Okay. Did you see any video put forth by the authors of this article number (c) and published in the Journal of Bone and Joint Surgery on "Intraoperative bacterial contamination in operations for joint replacement"?
A. Again, I will say right now that I do not recall exactly which reference documents the videos related to.
Q. So we could go through this entire list and, as you sit here today, you are not going to be able to tell me which one of these studies and/or articles and/or reports had a video that you relied

Page 225

upon in forming your opinions but did not cite to?
A. Yes, I do not have the recollection at this time.
Q. Okay. What would refresh your recollection?
A. I imagine watching the video and understanding what study that it related to would refresh my memory.
Q. All right. Have you been provided the depositions of the study authors in these cases? I see, for example, that you have been provided a copy of an article written by Belani, Albrecht, McGovern, Mike Reed and Christopher Nachtsheim. It is listed as Exhibit number...pardon me, reference number (n), provided to you by counsel. Do you see that one?
A. Yes.
Q. Do you know that every one of those authors has been deposed in connection with this litigation?
A. No, I am not aware of that.
Q. And they have not produced any of these depositions to you for your review in this matter, have they?
A. The depositions that have been

Page 226

produced to me are the same list that I have...I listed this morning.
Q. All right. And so, to the extent that this was an article that you relied upon in reaching opinions that you potentially intend to offer to the court and the jury in this matter, wouldn't you agree that the deposition testimony of these five authors outlining their methods and their conclusions would be important information that you have not been provided?
MR. GOSS: Objection to form.
THE DEPONENT: I have not...I am not aware of their depositions so I would not be able to comment at this time whether or not the contents of that deposition would have any influence on my opinions.

BY MS. ZIMMERMAN:
Q. All right. But you would agree they could impact your opinions?
MR. GOSS: Objection to form, asked and answered.
THE DEPONENT: At this stage, I don't know whether they would or not.

Page 227

BY MS. ZIMMERMAN:
Q. All right. Are you aware of whether or not there were videos made in connection with any of the published peer-reviewed studies?
A. Sorry, could you restate the question? I didn't get the first few words.
Q. Sure. Are you aware whether or not videos have been made in connection with any of these published peer-reviewed studies?
A. So, yes, as I answered earlier, I am aware that there are some videos related to some of the referenced documents that are shown here. I don't recall which ones they were.
Q. Okay. And I think...and, again, I am trying to get at which videos might they be. If they are on YouTube, I don't think that they are connected to any of the peer-reviewed journals that you have cited to.
A. I am sorry, on current reflection...
MR. GOSS: Wait for her to ask a question.

BY MS. ZIMMERMAN:
Q. Do you have any knowledge, as you sit here, about whether or not videos that you have been

Page 228

provided access to or directed to may have been videos of experiments performed by Mr. Albrecht?
A. It is possible. I can't recall.
Q. And, as you sit here right now, do you have any sense or knowledge about whether they might be videos of experiments conducted by Mr. McGovern?
A. I can't recall.
Q. Do you know if you have been provided any of the videos prepared in connection with Dr. Sessler and Dr. Olmsted's publication?
A. I do not recall.
Q. And you don't recall, as you sit here, whether it may have been videos connected to this Belani, Albrecht, McGovern, Reed, Nachtsheim paper either, correct?
A. I do not recall.
Q. In fact, as you sit here, you have no idea what the videos are; is that right?
A. I do not recall the authors connected with the videos.
Q. All right. Can you describe the videos in detail?
A. I cannot describe the videos in detail.

Page 229

Q. But you rely upon them in reaching and rendering the conclusions you have outlined in your report?
A. In watching the videos, they did provide a visual aid that helped me in forming my opinions.
MR. GOSS: I could use a bathroom break whenever you're ready.
MS. ZIMMERMAN: You can take a bathroom break.
MR. GOSS: Okay.

--- upon recessing at 3:56 p.m.
--- A BRIEF RECESS
--- upon resuming at 4:03 p.m.

MICHAEL KEEN, resumed
CONTINUED EXAMINATION BY MS. ZIMMERMAN:
Q. All right. Turning back to both Figure...the kind of hypothetical Figure 6 and Figure 7 in your report, Mr. Keen, it talks about...it attempts to depict the laminar airflow in the operating room, right?
A. Yes.
Q. Okay. And that laminar airflow,

Page 230

however you want to describe it, that unidirectional airflow is something you spend a lot of time and money and energy trying to achieve, right?
A. Yes.
Q. And the purpose of that system is to prevent the re-entrainment of pathogens, particles, bugs, all manner of things, right?
A. The re-entrainment of air carrying all manners of things back into that airflow, yes.
Q. All right. Good. And you read or you cite to Dr. Sessler's paper, right?
A. Yes.
Q. And he talks about potential protective effect, and there is even a...there is some discussion later in your paper about wound plume, and all of that, right?
A. Yes.
Q. All of that...taking all of that into account, you don't want to do anything to impact the protective effect, whether it's the plume theory or clearing the re-entrainment of air, right? You want to...this question is just getting all over the place. It's four o'clock and I'm tired. You would agree that the HVAC system is one of the most expensive systems in a hospital operating room,

Page 231

right?
A. No, not necessarily.
Q. Okay. You disagree that the HVAC system is one of the most expensive in a hospital operating room?
A. I wouldn't necessarily agree it's one of the most expensive.
Q. Okay. Would you agree that it is a system that you spend a lot of time and attention trying to ensure it is properly working?
A. Yes, I would agree with that.
Q. And you would agree that the reason that you care about making sure that it is properly working is to prevent re-entrainment?
A. That is one of the reasons to make sure, yes.
Q. All right. At the top of page 12 in your report, you have Figure 8, which includes the heat loads in the operating room, and as...do you see that?
A. Yes.
Q. All right. And as someone who has had responsibility for ensuring that the HVAC system is working, you would agree that it's important to know the heat sources inside of an operating room,

Page 232

correct?
A. Yes.
Q. And that is why you included it in your report, right?
A. Yes.
Q. And this chart that you included also includes design conditions, and that is quantified as BTUs per hour, correct?
A. Yes.
Q. Those are the numbers on the...the corresponding numbers for each of the heat sources, correct?
A. Correct.
Q. And this chart includes the patient, who is estimated to put out approximately 160 BTUs per hour, correct?
A. Correct.
Q. The chart then lists a surgical team of four people at 1,200 BTUs per hour, correct?
A. Correct.
Q. The support staff, again estimated at two, is approximately 600 BTUs per hour, correct?
A. Correct.
Q. And the reason that the support staff and the surgical team put forth more BTUs per hour

Page 233

than the patient has to do with the movement of both the surgical team and the support staff, correct? Or do you know?
A. I don't know for certain how they determined in this table the exact numbers of those design conditions.
Q. Okay. At any rate, this table also includes the anesthesia equipment, which is estimated to put forth 900 BTUs per hour, correct?
A. Correct.
Q. And the LCD monitors, which are estimated at 850 BTUs per hour, right?
A. Right.
Q. Surgical lights come in at an estimated 1,500 BTUs per hour, correct?
A. Correct.
Q. And then, according to this chart, overhead lighting comes in with the heaviest BTU per hour contribution at 2,400, correct?
A. Correct.
Q. So this chart then has a total of 7,610 BTUs per hour, correct?
A. Correct.
Q. And that is across a number of things, including both equipment and personnel in the

operating room, right?
A. Yes.
Q. And it was important enough in developing this particular chart to include a patient at even...even an anesthetized patient at 160 BTUs per hour, right?
A. Correct.
Q. And you would agree that all of the devices listed on this chart could produce thermal plumes, correct?
A. Yes.
Q. And you would also agree that thermal plumes can affect particle flow, correct?
A. Yes.
Q. All right. Do you know, as you sit here today, how many BTUs per hour a Bair Hugger contributes to an operating room?
A. As discussed earlier this morning, we had talked about the sort of general understanding of the heat source emitted from the Bair Hugger of the range of 400 to 450 watts.
Q. All right. Do you know what that is in BTUs?
A. It is roughly...something just a little over three times that number.

Q. All right. So you agree then that is more than the surgical lights?
A. Based on this chart...
Q. Yes.
A. ...that the 400 to 450 watts would be a greater number in BTU hours than the surgical lights.
Q. All right. And, in fact, it would be more...
A. Sorry, than the...what was the question again? Than the surgical lights?
Q. Yes.
A. No, sorry. If I do a 3 times 400, that is only 1,200, so, no, I don't agree that it's necessarily higher than that. Sorry, I misread that. I would think it's actually less, based on the exact calculation, potentially.
Q. Okay. And have you looked at the Bair Hugger manual to determine how many BTUs per hour the Bair Hugger contributes to the operating room?
A. Yes, I have.
Q. All right. And you are confident that that number is 400?
A. In general terms, as I said, from

what I...from my reading of the manual, the 400 to 450 range, in general terms, yes.
Q. Okay. But, at any rate, that is a significant BTU per hour contribution to the operating room load; you would agree with that?
A. The...if I looked at 1,200 and then as a total of roughly 8,800 BTUs per hour, it is not a significant portion of that total heat load. And certainly, the overall air supply and the impact on its air supply is not overly significant in considering the entire air supply.
Q. Well, the chart requires that we consider even the 160 BTUs per hour contributed by the anesthetized patient, right?
A. The chart isn't...
MR. GOSS: Object to form. Go ahead.
THE DEPONENT: The chart isn't a requirement; it's general depiction of potential heat sources found in an operating room.

BY MS. ZIMMERMAN:
Q. Okay. Well, taking a step back to the line of questions about thermal plumes, if the Bair Hugger is putting out 400 to 450 watts and

you're assuming then that that is somewhere in the neighbourhood of 1,200 BTUs per hour, you would agree that a Bair Hugger puts forth thermal plumes, correct?
A. Yes.
Q. And I have already lost...this is a...this chart is put forth by Price Industries, describing Critical Environments Engineering Guide; is that right?
A. Yes.
Q. All right. And Price Industries, anyways, apparently determined...by including an anesthetized patient in the total BTUs per hour in an operating room load, they determined 160 BTUs was enough to merit inclusion on their chart; that is fair, right?
A. Yes.
Q. But, for some reason, there is no inclusion of a patient...a forced air warming device, such as a Bair Hugger, correct?
A. There is no inclusion of the Bair Hugger or forced air warming device in this chart.
Q. Okay.
A. Again, I would say that this is a general chart that is not exhaustive of all the

Page 238

different types of heat sources in the operating room, but it was a general guide to what could be found as a heat source in an operating room.
Q. Sure. And as a person who is having to evaluate potential heat sources in an operating room, it's important to identify those heat sources that are going to have an impact on the laminar flow, correct?
A. Correct.
Q. All right. And would it surprise you, by the way, if the Bair Hugger actually puts out 1,600 BTUs per hour?
A. That would seem higher than what I have seen, yes.
Q. Okay. And that would be inconsistent with your recollection of the Bair Hugger manual?
A. Yes.
Q. Okay. Assuming, though, that it is 1,600 BTUs per hour, that would mean that the Bair Hugger was putting forward more BTUs per hour than every other thing listed on here, besides the overhead lighting, correct?
A. That is correct.
Q. All right. And assuming that your number is correct, that it was in the neighbourhood

Page 239

of 1,200, then the Bair Hugger would be equivalent to a four-person surgical team, correct?
A. Correct.
Q. All right. Did you...you were provided Dan Koenigshofer's report in this matter, correct?
A. Yes.
MS. ZIMMERMAN: And I don't normally do this, but I am going to mark his report as an exhibit here.

--- EXHIBIT NO. 9: Expert report of Dan Koenigshofer, dated March 31, 2017

BY MS. ZIMMERMAN:
Q. Before I get to this question, would you agree that putting...and assuming that the Bair Hugger does have, in fact, 1,600 BTUs per hour, would you agree that that would cause a change in the temperature around the surgical table?
A. I have not had an opportunity to study the change in temperature around a surgical table of the Bair Hugger at a 1,600 BTU level.
Q. Okay. And so you would defer to somebody who has done that study?

Page 240

A. Correct.
Q. All right. Turning to page 20 of Dan Koenigshofer's report...
A. Sorry, which page?
Q. Page 20.
A. Thank you.
Q. He has a subsection titled "15", and I will represent to you...well, he kind of titles it, he says "Effect of heated-air blanket on the dispersion of squames in an operating room", and he cites to Said Elghobashi, 2017. Do you see that?
A. Yes, I do.
Q. And I will represent to you that that is Said Elghobashi who has been offered as an expert on behalf of the plaintiffs in this matter, and I should also confirm an expert in computational fluid dynamics. There is an excerpt from Professor Elghobashi's report that is pasted into and adopted by Dr. Koenigshofer. Do you see that?
A. I do.
Q. And you see then that Professor Elghobashi concludes, starting at line 806:
"...With the blower off, the majority of the squames are dispersed by the ventilation airflow towards the outlet grilles. None of

Page 241

the squames actually rise to the level of the side tables or the OT [operating table]. In contrast, with the blower on..."
And I will represent to you that is the Bair Hugger.
"...a large number of squames are lifted upwards by the rising thermal plumes. Some of the squames are lifted above the surgeons' heads and are blown towards the OT [operating table] by the downward-moving ventilation air. Large number of squames are seen to be above the OT, several are surrounding the surgeons' hands, above the side tables, and some are very close to the patient's knee and the surgical site. Majority of the squames that come close to the surgical site were found to have originated from the sides parallel to the length of the OT..."
Have you ever seen Professor Elghobashi's report before now?
A. No, I don't believe I have.
Q. All right. And would considering the calculations that he has made and the experiments that he has done impact the opinions that you have rendered in this case?

Page 242

MR. GOSS: Objection to form, lack of foundation, CFD is beyond the scope of any opinions he is going to render in this case. If you can answer it, you may.
MS. ZIMMERMAN: Well, to the extent that the witness has an entire section designated "Turbulence in laminar flow designed operating rooms", I think that he has certainly opened the door to whether or not he is competent or qualified to offer testimony about the movement in a laminar airflow operating room. So I am questioning the witness as to whether or not he has been provided all the information he ought to be provided to reach a full and complete and reliable conclusion.
MR. GOSS: We are not offering him on any opinions related to CFD, but you can answer it if you understand the question.
MS. ZIMMERMAN: And, you know, to clarify further, to the extent that section 7 of the report is withdrawn, I am happy to abandon the line of questioning. But to the extent that we are going to talk about...or the witness is going...has offered testimony and

Page 243

a report talking about the impact of a Bair Hugger on the airflow in an operating room, it certainly seems to me that he ought to be provided all the information, certainly to the extent he is being offered as a rebuttal witness.
MR. GOSS: He is not an expert in CFD and will not be offering rebuttal opinions to Said Elghobashi. But, to the extent that you understand the question, I am not going to tell you not to answer it.
THE DEPONENT: In that discussion, I have forgotten the question, so if you could please repeat it.

BY MS. ZIMMERMAN:
Q. That is not the first time I have heard that, not just from you but...when lawyers start to have a dispute about what the questions are. So my general question was, you have not been provided a full copy of Professor Elghobashi's computational fluid dynamics analysis of the Bair Hugger device, correct?
A. Correct.
Q. And you understand that he has been

Page 244

offered by plaintiffs as an expert in computational fluid dynamics, who has performed specific calculations about the impact of a Bair Hugger device in the operating room environment; is that right?
A. I understand that only from your statement right now.
Q. Okay. And I will represent to you that that is what he has been designated to provide. I will further represent that he has conducted a computational fluid dynamics analysis through a range of mathematical formulas and access to code I could only begin to talk about, and run these models through a super computer, and that a small summary of some of his conclusions is encapsulated or incorporated into part of Dr. Koenigshofer's report, and which, I understand from your previous testimony, you had been provided and did, in fact, read. So, laying that foundation, you have at least seen this particular portion of Professor Elghobashi's report before, I trust?
A. Yes.
Q. All right. And do you have any reason to disagree with the conclusions that he has reached here?
MR. GOSS: Objection, lack of foundation,

Page 245

not offering any opinions related to CFD.
THE DEPONENT: Without seeing the full report, I can't, at this time, offer an opinion on Elghobashi's study.

BY MS. ZIMMERMAN:
Q. All right. But you would agree, as an engineer, it would be helpful to the conclusions that you ultimately reach in this case, to have a full and complete copy of all relevant information, including the computational fluid dynamics analysis performed by Professor Elghobashi?
MR. GOSS: Objection to form.
THE DEPONENT: Without having reviewed his study, I can't say whether or not it would have an impact on my opinions in my report.

BY MS. ZIMMERMAN:
Q. Okay. And, based on the summary that is provided and attached in Dan Koenigshofer's report, which you did review, there is nothing about these statements that impacts yours opinions; is that your testimony today?
A. There isn't enough context here for

Page 246

me to form an opinion about the content of the study that Elghobashi has performed.
Q. Okay. You don't believe that there is enough...there may not be a fulsome description of the methods by which he reached these conclusions, but you don't believe that these are sufficient conclusions that would be something you would take into account in reaching your opinions?
A. No, there isn't sufficient context there for me to render an opinion on this small excerpt.
Q. All right. Turning to Figure number 9, which, I believe, is...both Figure 9 and 10 are cited to endnote (m), which I believe is the Settles...no, I have misspoken. They are examples of airflow disruption of a surgical light and of surgical staff. Do you know...you cite to "The effect of obstructions and thermals in laminar-flow systems". The author is Whyte, and this looks like...I can't...do you know what this journal is, Journal of Hyg.?
A. I don't recall the name of the journal, but it is the reference for Whyte, these two diagrams are referring to.
Q. All right. And this is one of the

Page 247

papers you weren't sure whether it was provided to you by counsel or whether you had it prior to your involvement in this case; is that right?
A. That is correct.
Q. Okay. In any event, to the best of your recollection, have you seen this article before the last six months?
A. No.
Q. And do you have any idea, as you sit here, what method was used to capture these images?
A. I reviewed the paper that these images were taken from. At this current time, I can't recall the details of that paper.
Q. Did you include them in your report because they were visualizations of obstructions in an operating room?
A. That is exactly why I included them in the report.
Q. All right. And have you looked for any pictures that may be visualizing the impact of airflow disruption of a Bair Hugger?
A. There were images...there were images that I saw related to airflow with a Bair Hugger in some of the reports that I looked at. These images were to convey a certain description of a couple of

Page 248

examples of obstructions.
Q. All right. And you didn't include in your report an indication that the Bair Hugger may also be a heat source that impacts the...or that causes thermal plumes and impacts the airflow in an operating room, correct?
A. I did, in fact, talk about the heat generated by the Bair Hugger and the plume.
Q. I'm sorry, you did?
A. Yes.
Q. Okay. But you did not include a visualization of that in your report; is that right?
MR. GOSS: Object to form.
THE DEPONENT: I did actually include a different image that talked about that in a different area of the report.

BY MS. ZIMMERMAN:
Q. And where is that?
A. I refer you to Figure 13 on page 18.
Q. And who drew that?
A. That was a diagram that I drew myself.
Q. You drew both 12 and 13?
A. Correct.

Page 249

Q. Okay. And that is why there is no cites on this. Those are original to you?
A. Yes.
Q. I am jumping ahead of myself a little bit, but on page 17 in the middle of the page, you say:
"...In fact, from Figure 12, it has been shown that the thermal plume from the surgical site exerts force up against the downward flow and diverts it around the wound, if the ventilation has been designed at the right velocity..."
Is that right?
A. Correct.
Q. Is that what you're attempting to depict in Figure 12?
A. Yes, it is.
Q. And that is your drawing?
A. That is my drawing.
Q. Okay. And is this your attempt to visualize the thermal plume theory that is advanced by a handful of researchers?
A. More...
MR. GOSS: Object to form. Go ahead.
THE DEPONENT: Yes. This is the...this

Page 250

is my attempt to visualize the idea of the thermal plume, primarily as I describe it in reference to the studies done by Memarzadeh.

BY MS. ZIMMERMAN:

Q. Okay. And, in any event, you would agree that the goal is to not disrupt that protective cocoon that you describe, correct?

A. Correct.

Q. All right. And that if that protective cocoon is, in fact, disrupted, the risk of a surgical site infection or a deep joint infection is increased, correct?

MR. GOSS: Objection to form.

THE DEPONENT: That if that thermal plume is disrupted, that the risk to particles impacting on the surgical site is increased.

BY MS. ZIMMERMAN:

Q. You would agree with that?

A. Yes.

Q. Okay. Turning back to page 13 of your report, it starts out, at section c), "Potential risk of Bair Hugger disrupting supply airflow".

A. Yes.

Page 251

Q. Are you on that page? Okay. You say here the air...the second sentence says:

"...[The] Air eventually escapes primarily through the head and neck area of the patient..."

What is your basis for that statement?

A. The basis for that statement has to do with descriptive images and video that I have seen on the draping of the Bair Hugger blanket.

Q. So you are able to tell where the air is escaping based on photographs?

A. Photographs, description and video, yes.

Q. Do you recall...you weren't provided a copy of Michael Stonnington's report?

A. That name is not familiar to me.

Q. Okay. Are you aware of reports from surgeons and orthopaedics that airflow may be escaping not just from the head and neck?

A. I am not aware of that.

Q. Okay. Were you told that you should assume that the air eventually escapes primarily through the head and neck area of the patient? Were you told to assume that by counsel?

A. That was information that was from

Page 252

the documentation and video that I reviewed.

Q. Okay. So this also comes from the video that we don't know whose video it is?

A. No, sorry, in this case, I have seen...and this refers to a 3M video that...is it a 3M video...a video on YouTube that describes the application of the blanket and the ceiling and the draping. And that is different from the videos I was talking about before the break.

Q. All right. So that is another separate video that is not identified on your list of references; is that right?

A. Correct. That was one that I saw from YouTube.

Q. So, just so I understand, are there multiple videos on YouTube that you're relying on that aren't listed on the references?

MR. GOSS: Object to form.

THE DEPONENT: Some...

MS. ZIMMERMAN: I don't know how to fix that.

MR. GOSS: Well, I think what I am struggling with is, what "relying on" means may be different from his Canadian understanding than what we use in American

Page 253

litigation.

THE DEPONENT: So, most of the...most of the videos that I looked at I am not relying upon for the basis of my opinions, but they were, again, as I tried to explain before the break, visualizations that were helpful to support what I was reading. So I didn't change...the videos didn't change my opinions but just helped as a visualization, if that explains it better.

BY MS. ZIMMERMAN:

Q. All right. Did you see any videos put forth by someone who has a different interpretation of the impact of the Bair Hugger on the operating room?

A. Sorry, can you restate that question?

Q. I will try. So, you said that you saw a 3M video on YouTube that apparently addresses...and I don't know what point it addresses...it addresses how the blanket is attached to a patient?

A. As I said, how the blanket is attached and how the draping is done in the application of the Bair Hugger blanket during a

Page 254

surgery.
Q. All right. Is this a video put forth...is Jennifer Wagner in this video?
A. I have no idea.
Q. You have no idea who the...
A. This was a YouTube video, and, again, it was a visualization to help understand.
Q. All right. Well, walk me through that video what you remember about it. It's on YouTube?
A. Yes.
Q. You have associated that one at least with 3M in some way?
A. And, sorry, my reference to 3M might be incorrect. It was a video I YouTubed about the Bair Hugger application of the blanket and the draping, and it came up. And I didn't, certainly, reference any people who were in the video or anything like that, nor, I don't think, I knew who was in the video.
Q. Sure.
A. But I just watched the application, a visualization of how this was applied. So how the...you know, it was a typical hip surgery, how they applied the blanket, how they connected the

Page 255

hose, how draping was done with adhesives and so forth, or how it was set up. And so that was the...that was the basis of the video. Again, a visualization of what had been described previously as to the process by which a Bair Hugger blanket was applied.
Q. Okay. And the focus of that video sounds like it was on draping and attaching the blanket to the machine?
A. And on the patient, yes.
Q. Did counsel send you a link to this video?
A. No. I searched that video independently.
Q. Okay. So, in searching a video... searching for this video, you came up with a video on YouTube about Bair Hugger and draping?
A. Yes.
Q. What other videos came up on YouTube about Bair Hugger?
A. On this specific one, I was looking specifically for that.
Q. Okay.
A. So I couldn't tell you on other topics with Bair Hugger...you know, there are other

Page 256

videos that certainly I saw. But, again, they did not provide any new independent information that I wasn't...that I had to rely upon to provide the opinions in my report, but were more visualizations of information I had already read.
Q. So the question or the statement that I was asking you about is:
"...Air eventually escapes primarily through the head and neck area of the patient..."
And I have asked you what the basis is for that statement, and you have directed me to a 3M video on YouTube about draping. How do you know from that video that the air eventually escapes primarily through the head and neck area of the patient?
A. Based on how the description of how the adhesives are applied, how different ports are closed off, and how...where it is left open, that shows where the air would primarily escape from.
Q. All right. How long is the video?
A. If I had...approximately four minutes.
Q. Have you seen or touched a Bair Hugger blanket itself?
A. I have not.
Q. All right. Can you describe a Bair

Page 257

Hugger blanket model 522?
A. I am not familiar with the model numbers.
Q. Do you know what an upper body blanket looks like?
A. Yes.
Q. Describe it for me.
A. It's a paper blanket with perforated holes that looks like the upper portion of a body, and unfolds and is applied to the patient.
Q. Do you...in the video, how was the patient, or the model, I guess...I assume it wasn't a real surgery...how was the model positioned?
A. It was set up for a hip surgery and...
Q. Was the patient on...or the model on the back or on the model side or...
A. The person was on their side.
Q. Okay. And the video lasted about four minutes?
A. Approximately. It could be five, it could be three, just approximately, yes.
Q. Do you know whether there were time lapses in the video?
A. No, I don't think there were any time

Page 258

lapses.
Q. Was the video narrated?
A. I believe it was. I believe it was, yes.
Q. And does part of that narration include a conclusion by someone involved in the video that...
A. No.
Q. ...the air is leaving primarily through the head and the neck?
A. It wasn't so much a conclusion as it was a description of how it was applied.
Q. All right. And a description of how the blanket is applied to the person?
A. Yes.
Q. Okay. Was there a conclusion by whomever is narrating on the video about where the air is primarily escaping?
A. I don't recall a conclusion by the narrator.
Q. So that was a conclusion that you reached by looking at the video?
A. By looking at the video, that visualization, it confirmed a conclusion of...and, again, I had heard before that the air, primarily on

Page 259

those upper body blankets, escape through the neck and head area of the patient, and I can't, to my memory right now, recall from which citing of what I have looked at.
Q. All right. And so, wherever you heard it or read it, it was your assumption that the air primarily escapes through the head and the neck, correct?
A. Correct.
Q. All right. And if it turns out that that assumption is incorrect and that air escapes from places other than the head and the neck, would that impact the opinions that you have offered in this case?
MR. GOSS: Object to form.
THE DEPONENT: It is my understanding that air does escape from other areas. It's primarily from the head and the neck, as I said, and that is the majority of it. I would need to review that information to see if it changed my opinions.

BY MS. ZIMMERMAN:
Q. All right. And how would you go about quantifying what it means to have the majority

Page 260

of the air escaping from the head and the neck? Or how did you go about quantifying that, I guess?
A. It was a qualitative assessment of the quantity. It wasn't the exact measurement. And so...and I am not sure whether an exact measurement is necessary for the opinions that I am rendering upon it. So that is...it was based on general sort of proportions.
Q. So this sentence is...you know, the second sentence in your section about the potential risk of the Bair Hugger disrupting the supply airflow, is there something about the air that was escaping through the head and the neck that was coloured, or in other...in some other way visually appreciable to you as a person YouTubing something on the computer?
A. The air was not covered, but the way in which the draping was done, it..in the video, it visualized what I had heard before, that it seemed intuitive that the...primarily the air would escape through head and neck area.
Q. But there was nothing about...there wasn't, you know, smoke or bubbles or some other kind of objective tool for you to measure the air escaping from one spot or another, correct?

Page 261

MR. GOSS: Object to form.
THE DEPONENT: No.

BY MS. ZIMMERMAN:
Q. All right. Where did you hear that the air eventually escapes primarily through the head and the neck of the patient?
A. Where did I first hear that?
Q. Yes.
A. I don't recall.
Q. And then you go on in your report to say that:
"...[The] Adhesive strips help seal edges of the sterile drape adjacent to the surgical site..."
Is it your belief, by the way, that the drape is sterile? I assume so because it says "sterile drape".
A. I have not done any testing on the drapes. This is based on my general understanding that, in the start of a surgery, that new drapes are sterile, but I have nothing to support that.
Q. Okay. And you have never opened a Bair Hugger blanket yourself, right?
A. I have not opened a Bair Hugger

Page 262

blanket myself.
Q. And so, you don't understand, from looking at the outside of that package, that that is not actually a sterile product, correct?
A. I have not opened one myself, and I don't have any understanding of the packaging for a Bair Hugger blanket.
Q. Okay. But, at any rate, the report that you have prepared indicates that the "adhesive strips are going to help seal the edges of the sterile drape adjacent to the surgical site, so that escaping air does not blow directly in the direction of a surgical site", correct?
A. Correct.
Q. And what is the basis for that statement?
A. Again, based on the way that...the way that it is described that it is applied and confirmed again, notionally, by the video that I watched, where you can see the adhesive strips applied.
Q. All right. Where are those adhesive strips on the Bair Hugger?
A. Some of them were on the Bair Hugger and some of them were on the drapes. And I don't

Page 263

recall the exact locations, but there were a number of different adhesive strips in the whole application of the Bair Hugger and draping.
Q. Do you have any idea how many holes there are in a Bair Hugger blanket?
A. No, I do not.
Q. All right. Do you know how they might be placed on the Bair Hugger blanket?
A. I understand there were a number of them distributed across the blanket, but I don't know the exact distribution.
Q. Your next paragraph in your report says:
"...A question has been raised that forced air warming devices pose surgical site infection risk by disrupting the laminar airflow, allowing bacteria to enter the surgical site or impede the ventilation system's ability to remove contaminants from the surgical site..."
As an engineer, what did you do to address that question?
A. As an engineer, I reviewed the various studies that I had before me to determine an opinion on whether or not the forced air warming

Page 264

device appeared to have an impact on that.
Q. All right. And you did some additional independent research; is that right?
A. By independent research, I refer only to looking at other documents.
Q. Okay. And that includes your Google search?
A. Correct.
Q. Okay. Or searches. Did you find anything that suggested that forced air warming devices do pose surgical site infection risk?
A. There were some papers that hypothesized or claimed this as part of their papers, yes.
Q. All right. And did you discount the conclusions reached by those authors?
A. I would have...
MR. GOSS: Object to form.
THE DEPONENT: I would have to look at which ones you're speaking of specifically.

BY MS. ZIMMERMAN:
Q. So, in approaching this question about whether or not forced air warming devices pose a surgical site infection risk by disrupting laminar

Page 265

airflow and therefore allowing bacteria to enter the surgical site or impede the ventilation system's ability to remove contaminants from the surgical site, if I understand your testimony, you found some articles or were presented with some articles that concluded that is, in fact, the case, correct?
A. I did find some, yes.
Q. All right. And in reaching the opinions that you have offered in this case in support of 3M, have you discounted those conclusions?
MR. GOSS: Objection to form.
THE DEPONENT: So, in the review of some of those articles, yes, I had a rebuttal to what they were saying, yes.

BY MS. ZIMMERMAN:
Q. I think that when we talked about deposition testimony that you had provided earlier today, you said that you did not have any 3M or Arizant employees; is that correct?
A. Sorry, I don't have any employees?
Q. You didn't have...you were not provided with any of the...I don't even know what the number is, 20-some employee depositions that have been taken in this case, correct?

Page 266

A. I do not have that. I have a list of depositions I shared with you earlier.
Q. Okay. And, similarly, we have a procedure in the American judicial system, we call it a 30(b)(6) deposition, and that means a company picks a person and designates them as their official spokesperson. So, anything that person says is binding on the company. In this instance, I will ask you to assume that 3M designated a man by the name of Al Van Duren as their 30(b)(6) corporate representative. I assume you have not been provided the company's deposition of Al Van Duren, have you?
A. I recall something from Al Van Duren. I don't think it is a full deposition, but I have something from Al Van Duren, and I can't recall exactly what that was, to be honest.
Q. All right. And I will ask you to assume...given you haven't been provided with that deposition, I will ask you to assume that, in that deposition, the company has admitted that every study done thus far shows an increase in particle count when the Bair Hugger unit is turned on in an operating room. Is that relevant to the opinions that you offer in this case?
MR. GOSS: Objection to form, and

Page 267

foundation.
THE DEPONENT: So I don't know the context to which that statement was made. I would have to review it to understand what that was relying upon.

BY MS. ZIMMERMAN:
Q. All right. You understand that surgeons care about particle count in their operating room, correct?
A. I don't know. That is a statement I can't agree or disagree with.
Q. You would defer to a surgeon on whether they care...
A. On whether they care, yes, I would defer to them, yes.
Q. Okay. How about from an HVAC standpoint, you would agree that HVAC engineers want to have the least number of particles in an operating room as possible, correct?
A. Correct.
Q. And you...we talked very briefly earlier about a poor gentleman I keep butchering his name, Farhad Memar...
A. Memarzadeh?

Page 268

Q. Memarzadeh. Okay. You know him in some regard?
A. Yes, I do.
Q. And how do you know him?
A. I know him from my ASHRAE committee work.
Q. All right. And would you agree that he holds himself out as an expert in airflow?
A. Yes.
Q. And you would, I assume, defer to him on matters regarding airflow in an operating room?
A. Yes.
Q. And you understand from some of the materials that you have been provided in this case that Dr. Memarzadeh, that his work...that he agrees that the Bair Hugger disrupts laminar airflow, correct?
MR. GOSS: Object to form, foundation.
THE DEPONENT: I don't recall it saying the exact wording like that, but there is some wording in the...in Memarzadeh's paper that talks about the buoyant force that affects the airflow.

BY MS. ZIMMERMAN:

Page 269

Q. All right. And do you know if Dr. Memarzadeh was looking at...well, do you know which Bair Hugger blanket he was looking at in his test?
A. I can't recall if the model of the blanket was cited in his paper.
Q. Can you describe his study at all?
A. Which study are you asking about?
Q. The study that he did in 2010.
A. I refer to the 2010 study by Memarzadeh on page 16 and 17 of my report.
Q. And just by way of background, is this an NIH study, or is this a study authored by him, amongst others?
MR. GOSS: Do you need to look at the study?
THE DEPONENT: I do.

BY MS. ZIMMERMAN:
Q. And, in fact, the summary that you have in your report at the bottom of page 16 says: "...In a CFD study, NIH analyzed laminar airflow disruption and room airflow patterns to determine the effect of squame impingement from personnel surrounding the

Page 270

operating table as a source of surgical wound infection. It was found that the downward velocity from the ceiling laminar diffuser is slightly less strong with the forced air warmer operating than when the air warmer is off..."

That was your summary of Memarzadeh's 2010 paper, correct?

A. That is the first half of my reference to it. There is more reference on 17. My understanding is the 2010 reference to Memarzadeh is actually a response...a letter to an editor, but within this, it refers back to a study that he did back in 2002.

Q. Right. And when you reference NIH, is that the position that Dr. Memarzadeh holds, and is he writing on behalf of the entire organization, or on behalf of himself personally?

MR. GOSS: Objection, lack of foundation.

MS. ZIMMERMAN: If you know.

THE DEPONENT: So, my understanding is Memarzadeh works at NIH, and so, whether he is representing NIH or himself in this paper, I do not know.

Page 271

BY MS. ZIMMERMAN:

Q. Okay. In any event, Dr. Memarzadeh's study back in 2002, are you aware that he was only looking at the 505 Bair Hugger device...

MR. GOSS: Object to form.

MS. ZIMMERMAN: 2010, I am sorry.

THE DEPONENT: I am not aware of the model number he was looking at.

BY MS. ZIMMERMAN:

Q. All right. And are you aware that he was also only looking at the underbody blanket?

A. I am not aware of the model he was looking at.

Q. And are you aware that there is both an upper body blanket and an under body blanket?

A. Yes, I am.

Q. And a number of other blankets that we don't seem to talk much about in this case. You're aware, anyways, that there are multiple Bair Hugger disposable blankets for use with this...

A. I am aware that there are multiple different blankets.

Q. Okay. Have you seen this study?

A. Yes, I have seen this study.

Page 272

Q. And which one are you referring to?

A. The 2002 study?

Q. Yes.

A. I have seen the 2002 study, yes.

Q. 2002, 2010.

A. The 2010 letter, and both are referenced in my report.

Q. There is also a 2010 study, isn't there? I might have a copy of it. You have a copy of his letter to the editor in front of you?

A. I do.

Q. Does he reference a study in that letter?

A. Yes, he does...sorry, I don't know if he does. He cites the article itself.

MS. ZIMMERMAN: And we are up to Exhibit 10.

--- EXHIBIT NO. 10: Letter to the Editor, written by Dr. Memarzadeh, submitted to the Journal of Hospital Infection, 2010

BY MS. ZIMMERMAN:

Q. And is Exhibit 10 the same letter to the editor that you were referencing in your notes?

Page 273

A. Yes.

Q. Although this one has a highlighted section?

A. Yes.

Q. All right. And is it your understanding that this letter references only back to the 2002 study that was done?

MR. GOSS: If you want to go off and give him time to read it...

MS. ZIMMERMAN: Sure.

MR. GOSS: ...so it doesn't count against your time.

MS. ZIMMERMAN: That is fine.

--- upon recessing at 4:55 p.m.

--- A BRIEF RECESS

--- upon resuming at 5:00 p.m.

MICHAEL KEEN, resumed

CONTINUED EXAMINATION BY MS. ZIMMERMAN:

Q. All right. Mr. Keen, we took a short break while you reviewed this Exhibit 10, which is a letter to the editor in the Journal of Hospital Infection in, I think it is 2010. Do you recall that?

Page 274

A. Yes.
Q. And does this letter to the editor reference additional testing with respect to both Memarzadeh and Moretti conclusions?
A. Yes.
Q. All right. And have you seen the additional...the results of the additional testing referenced in this letter?
A. So it references studies of Memarzadeh for 2002 and 2004 in the referencing. I have reviewed the 2002 reference. It also speaks in its review of the Moretti paper of testing that they have done, and which appears to me to be additional testing on...additional testing using a Bair Hugger device.
Q. Okay. And would you agree the beginning of the second paragraph, this letter to the editor says:
"...The literature indicates that a forced-air warmer system may disturb the operating room laminar airflow and increase the risk of nosocomial infections..."
Is it your understanding that may be one of the precipitating reasons for this letter to the editor?
A. I am thinking that the literature he

Page 275

talks about there is the Moretti article.
Q. Okay. And, in any event, that is the characterization of the literature at that time in this letter to the editor, correct?
A. I believe...
MR. GOSS: Objection, the document speaks for itself.

BY MS. ZIMMERMAN:
Q. And if it is characterizing Moretti, you would agree that Moretti shows an increase in the risk of nosocomial infections with the use of forced air warming, right?
MR. GOSS: Object to form, lack of foundation.

BY MS. ZIMMERMAN:
Q. Have you seen Moretti, by the way?
A. I have seen Moretti, and I refer to it within my report as well.
Q. And were do you refer to Moretti?
A. On page 21.
Q. All right. And then the letter to the editor for the Journal of Hospital Infection, towards the end, goes on to say that:

Page 276

"...Although the squames from the anaesthesiologist..."
And I am looking at the second-to-last paragraph. It says:
"...Although the squames from the anaesthesiologist location move upwards due to thermal plume and away from the surgical site, supply flows largely dictate airflow pattern. When the forced-air warmer is operating, the downward velocity from ceiling laminar diffuser is slightly less strong than when it is off. With the same supply air temperature, the air temperature around the surgical table is warmer when the forced-air warmer is operating. Forced-air warmers seem to cause minimal disruption to laminar airflow systems that help protect the surgical site from contaminated particles sourced from surgical staff..."
Did you see that?
A. Yes.
Q. So you would agree then that there is a conclusion in this letter to the editor that there is some disruption of the laminar airflow when the forced air warming system is on, correct?

Page 277

MR. GOSS: Objection, the document speaks for itself.
THE DEPONENT: I would agree that there was a buoyant force, a minimal buoyant force provided by the forced air warming blanket that is reflected in my report as supporting what...reflecting what Memarzadeh says here about the minimal disruption to the downward flow, as indicated on pages 16, 17, 18 of my report.

BY MS. ZIMMERMAN:
Q. So, with respect to the content of the letter to the editor that is Exhibit 10 to your deposition now, you would defer to the authors of that paper as to what their conclusions were, correct?
A. Yes.
Q. And there is nothing in your report that is intended to be a rebuttal to that letter to the editor, is there?
A. No.
Q. All right. And you understand that Moretti does show an increase, right?
A. My understanding of the conclusion of

Moretti that I pulled is that there was an increase, primarily based on the patient's entry into the operating theatre, and that the increase after the application of the body warming system was comparably lower to that load that was present at the time of the placement of the patient.

Q. Well, setting aside the reasons that may explain the increase in...there was, in fact, an increase in the Moretti study, correct?

MR. GOSS: Asked and answered.

MS. ZIMMERMAN: You can go ahead and answer.

THE DEPONENT: I would love to repeat what I just said. There was an increase shown during the study for different reasons, and so...

BY MS. ZIMMERMAN:

Q. Okay. Let me just stop you there, because my question isn't about the reasons; it's about whether or not an increase was shown.

A. In the study?

Q. Yes, in Moretti.

A. At some point during the study, he shows an increase.

Q. Thank you. So, turning to page 13 of your report, you had some criticism, it seems, of the use of bubbles to study particles in airflow. Do you see that? And you point, at least initially, to two different studies you attribute to Albrecht and one to Legg, whereby the bubbles were generated to simulate airflow patterns. And it says:

"...of bacteria attached to particles with and without a forced air warming system on..."

Do you recall that?

A. Yes.

Q. And you are critical, as I understand it, of using bubbles to try to study these particles; is that right?

A. Yes.

Q. Why is it inappropriate to use bubbles as a proxy for particles?

A. In my opinion, I did not find bubbles to be an appropriate representation of the particles in question, based on the relative size and buoyancy and resulting suspension times of those bubbles versus the particles. And, in support of that, I referred to a document that I reference on this page in reference (q) by Kerho, where they have done

studies that show that bubbles are generally not reliable to accurately represent airflow, and should only be used for qualitative-type measures.

Q. And what is a qualitative-type measure?

A. Just sort of a general...a general representation, as opposed to a measurement of flow patterns, is what I took that as.

Q. All right. Would you agree that a visualization could be a qualitative representation?

A. Yes.

Q. Such as the pictures that you included at Figures 9 and 10?

A. Yes.

Q. All right. And does the fact that they are qualitative representations discount their potential relevance, in your mind?

A. No, because my use of those photos is to represent the fact that there are obstructions to an airflow, and that just qualitatively supports the fact that there is a disruption to...in a visual form, that there are disruptions to the airflow, but doesn't try to measure how that airflow is disrupted or where particles might flow in that disruption, and simply shows as a visualization, generally.

Q. All right. And so, you think that it was inappropriate to use bubbles to serve as visualizations of particles in these experiments; is that accurate?

A. Yes. In my opinion, I did not feel that the bubbles accurately represented the flow patterns that might be expected of the particles.

Q. All right. And what do you base your opinion on?

A. Both on, again...

Q. Kerho?

A. ...Kerho's study and my own assessment of the characteristic of a bubble versus the particle and the relative sizes and characteristics and densities.

Q. Okay. So, starting, I guess, with the second part there, your own experience with particles, tell me about what your experience is with particles and characterizing particles.

A. Just, again, from sizes, the bubbles appear to be a size that is larger than the particles that are in question that we were looking at from a bacteria standpoint, and the density of such particles, as described, would be, again, a different density than what the bubbles would be, combined with

Page 282

Kerho's experiments talking about the natural...the different buoyancy of the bubbles, to me, did not, in my opinion, form a representation that was accurate of the particles.

Q. Is it your testimony that bubbles are more or less than dense than particles in the air?

A. Of different density.

Q. Of different density?

A. Yes.

Q. But greater density or less density?

A. It depends on the particle or the groupings of particles or what the particles are attached to.

Q. All right. Are there any bubbles that you think could be appropriate proxies for particles in the air?

A. Not in my opinion.

Q. All right. Have you ever done any particle measurement?

A. I have not personally done particle measurement, but I have contracted for particle measurement to be conducted.

Q. So you have hired other people to do particle sampling and...

A. Yes, I have.

Page 283

Q. All right. But you have never personally done particle sampling?

A. No, I have not.

Q. You are not familiar with any of the tools that are used to measure particles in the air?

A. I am familiar and seen some of the tools that were used by some of these contracted individuals, but I have not used them myself.

Q. All right. And it is not something that you are personally trained to use?

A. It is not something I am personally trained to use.

Q. All right. And it is not something that you would be in a position to offer any testimony about calibration or accuracy of measurements, or anything like that, because you don't have training in that field, correct?

A. I would not offer any testimony on the calibration of such equipment.

Q. All right. And harkening back then, I think that you were provided the deposition of Michael Buck in this matter; is that right?

A. Yes.

Q. I know the names all probably start to run together for all of us, especially at this

Page 284

time. He is a plaintiffs' expert who conducted an experiment with respect to particles coming out of the Bair Hugger. Does that ring a bell?

A. I did not get the opportunity to read Buck's deposition.

Q. Okay. Were you ever provided a copy of his report?

A. No.

Q. So you're not going to be offering any opinions with respect to the particle measurements that Mr. Buck did in his experiment?

A. I am not offering any opinions about Buck's experiments.

Q. Okay. And with respect to the criticisms that you offer about the use of bubbles in studying particles in airflow, you refer heavily to this Kerho article at letter (q), the "Neutrally buoyant bubbles used as flow tracers in air"; is that right?

A. Yes. Kerho, I rely on, yes.

Q. Okay. And that was one of those articles where you weren't sure if you had it...if it was produced to you by counsel, or if you happened to come across that in your own research; is that right?

A. That is correct.

Page 285

Q. But, in any event, this is something that would have been new to you over the course of your work in this matter; is that fair?

A. This article was new to me, yes.

Q. Okay. And have you, prior to your work in this case, ever considered the use of neutrally buoyant bubbles in tracing particles or simulating particles?

A. No.

Q. Moving to section ii) here, "Particle characteristics", you offer opinions about the ability of a particle to remain airborne, and say that:

"...The ability of a particle to remain airborne is dependent on the size and density of the particle..."

What do you base that on?

A. I base that both on my own knowledge about particles, and in here I also refer to a reference (r) by Noble.

Q. And I am sorry, which number is that?

A. (r).

Q. (r), Noble, "The size distribution of airborne particles carrying microorganisms"?

A. Yes.

Page 286

Q. And that was published in 1963?
A. Yes.
Q. And that is from that same article I couldn't...that same journal I couldn't identify before, the Journal of...I shouldn't even guess...Hyg., Camb.?
A. Yes.
Q. Do you know what journal that is?
A. I don't recall.
Q. All right. And that is another one that you weren't sure if it had been provided to you by counsel, but, in any event, is new to you since the start of this litigation, correct?
A. That is correct.
Q. And then you continue to say that, essentially, whether or not an "airborne particle may carry a microorganism is determined by two opposing factors, gravity, which tends to eliminate the large particles, and the chance that a particle will carry a viable organism, which is likely to increase with the size of the particle". What do you mean by that?
A. And that is a reference from Noble, but by that I mean that the larger that a particle is, the more it's affected by gravity, and also, the larger that a particle is, the more likely it is to

Page 287

carry another contaminant in combination with it.
Q. And did you have any experience with characterizing particles prior to involvement in this case?
A. Yes.
Q. When?
A. I have been involved with...in the...in the design and application of isolation rooms, we have worked on understanding the characteristics of airborne versus droplet versus contact infection transmission toward the determination of what should be in the standards for design of these isolation rooms, and which application applies to which.
Q. And when you have been a part of those conversations, it has been a group conversation, I gather?
A. Yes.
Q. All right. And who else has participated in those conversations with you?
A. Members of the two committees... multiple committees between CSA and ASHRAE, actually, as well as in infection control practitioners, epidemiologists, directors of infection control.
Q. And with respect to particles

Page 288

generally, and certainly their ability to carry microorganisms, is it fair to say that you would defer to an infectious disease specialist in that regard?
A. Correct.
MR. GOSS: Object to form.
THE DEPONENT: Yes, I would.

BY MS. ZIMMERMAN:
Q. And you would also defer to a microbiologist in that regard?
A. Yes, I would.
Q. All right. And are you offering any expert testimony with respect to the ability of a particle to carry microorganisms?
A. I am sorry, if you could help me...explain to me what you define as "expert testimony"? I am certainly providing opinions within my report about how particles move in the air and how they are attached to other particles.
Q. Right. And what I am trying to understand is, you know, you have two sentences here about particle characteristics, and one of them has a citation to this 1963 article by Noble. And I want to know, to the extent that you are characterizing a

Page 289

particle's ability to remain airborne and potentially carry microorganisms that could cause an infection, what is that based on; your experience?
A. Just these two sentences?
Q. Well, I mean, that is what you have identified in your report about what you are, I gather, about what you are prepared to say to a court or a jury in this case, correct?
A. Sorry, I'm confused. There is more than two sentences I talk about particles in the report. So I am not sure if you're referring to just the two sentences or the entirety of the report or...
Q. Well, this, we're talking about particle characteristics. And I have asked you about these two particular sentences. I mean, unfortunately, we are slogging through this whole thing, as you can see. But, to the extent that you are offering testimony or attempting to offer testimony in this matter...
A. Yes.
Q. ...about a particle's ability to remain airborne and whether or not a particle has the capacity to carry microorganisms, which potentially cause infections...
A. Right.

Page 290

Q. ...I want to know what that is based on.
A. So that is based on, again, my review of relevant documentation and my experience to do with, as I mentioned, the characteristics of different infections and transmission of infections by either droplet, contact or airborne.
Q. Okay. And so, I asked about citations, at least, and that is the Noble piece that you have here?
A. Right.
Q. And then I asked you about experience, and you said, I think, that you sit on some committees that have addressed these issues. Is that fair so far?
A. Yes.
Q. We are on the same page. Okay. So, I said, "Who else is involved in those committees?" And I assumed that you would defer to a microbiologist or an infectious disease specialist with respect to...
A. And a number of them are on the committee, yes, as I mentioned.
Q. All right. And, in any event, if microbiologists and/or infectious disease physicians

Page 291

come to trial in this case and offer testimony about particulates and their propensity to carry microorganisms, you're going to defer to their testimony in that regard?
A. Yes.
Q. Okay. Now, you list in Figure 11...it's a list of a number of different nosocomial pathogens that can become aerosolized; is that right?
A. Yes.
Q. And that comes from Kowalski, right, in 2012?
A. That is correct.
Q. All right. And what was the purpose, in your mind, of including this particular table?
A. It represents the various relative sizes of a number of different viruses, bacteria and fungi, and other pathogens to have an understanding of what the size of concern that we are dealing with in this matter here.
Q. Okay. And you understand that Kowalski's publication here has been cited by Dan Koenigshofer and I believe also Michael Buck as well, although you wouldn't know that because you didn't have his report. But you did see it, however, in Dan Koenigshofer's report, correct?

Page 292

A. Yes.
Q. All right. And this is a pretty standard publication that is relied upon and considered authoritative by members of ASHRAE and other...
A. I don't know who relies upon it.
Q. All right. You relied upon it, at least, right?
A. I did, yes.
Q. So you find it authoritative?
A. Yes.
Q. Okay. So, right below the end of Figure 11, your text starts:
"...The science of controlling infections caused by airborne microorganisms is a complex mixture of engineering, particle physics, microbiology, and medicine..."
Right?
A. Yes.
Q. All right. And then, just to parse that down, I think that you've agreed that, with respect to microbiology, you're going to defer to microbiologists. You don't have training in that; is that right?
A. That is correct.

Page 293

Q. Okay. And, similarly, you are not a physician, correct?
A. That is correct.
Q. So you are not going to be offering any testimony in this case with respect to issues regarding medicine, correct?
A. That is correct.
Q. All right. Similarly, with respect to particle physics, I think that you've said that you're going to defer to the particle physics experts in computational fluid dynamics; is that right?
A. That is correct.
Q. Okay. And with respect to engineering, you would defer to, I assume, folks that have gone about in designing an HVAC system for a hospital, correct?
MR. GOSS: Object to form.
THE DEPONENT: I would also rely upon my own opinions when it comes to engineering of hospital design.

BY MS. ZIMMERMAN:
Q. Okay. But you have testified already this afternoon that you would not feel comfortable designing an HVAC system for an operating room alone,

Page 294

correct?
A. I don't recall the earlier testimony, but I am not...my current profession is not one of design. I certainly lead design activities for the hospital, and I am involved in design...making decisions as part of the standard activities I am involved with. But I am not employed today, in my role, as a design engineer. Despite my training as a mechanical engineer, that is not my current role.
Q. Okay. And you have not personally designed an HVAC system for an operating room by yourself before, correct?
A. Correct.
Q. All right. And you only, to this point, assisted in the design of one HVAC system that was used in a hospital in the United States at this point, correct?
A. No. That is one that I assisted in the design in the United States when you asked about facilities in the United States. I certainly have been involved in assisting with the design of systems at my own hospital.
Q. Okay. And let's break that into two pieces. With respect to designing HVAC systems for use in ORs in the United States, you have done that

Page 295

once before, correct?
A. That is correct.
Q. All right. But you have done some other HVAC design work in teams in Canada, right?
A. Yes.
Q. Okay. And so, with respect to the next kind of paragraph that talks about what I would characterize as particle physics, talking about how particles settle over time, is it fair to say that you would defer to a particle physics specialist in matters of this regard?
MR. GOSS: Object to form.
THE DEPONENT: Yes, I would.

BY MS. ZIMMERMAN:
Q. And so, while you offered criticisms of what conclusions and methods Albrecht and Legg may have conducted and ultimately reached, you would defer to other folks on whether or not those were appropriate methods and conclusions, correct?
MR. GOSS: Object to form.
THE DEPONENT: I offered opinions related to those articles, and I felt qualified to offer those opinions. Where it related to particle physics, as you ask, then I would

Page 296

defer to someone who is specialized in particle physics.

BY MS. ZIMMERMAN:
Q. Okay. Would you agree that the movement of particles in the operating room is going to be a matter of particle physics?
A. I would agree that it is a combination of the HVAC system design characteristics and particle physics.
Q. All right. Let's move on to page 16. We're going to get now to the "Review of particle counting studies", and you have four here, I think. Legg from 2012, correct?
A. Yes.
Q. Sessler in 2011?
A. Yes.
Q. McGovern in 2009?
A. Yes.
Q. And then Memarzadeh in 2010, correct?
A. Yes.
Q. And those are the four studies that you reviewed with respect to particle counting, correct?
A. Yes.

Page 297

Q. So in the Legg study, which is in 2012...and, again, you were not provided the deposition of Mr. Legg, were you?
A. No, I was not.
Q. Okay. So your understanding of the methodology employed by Mr. Legg and his co-authors is limited to what is described in the article, correct?
A. Yes.
Q. And that was provided to you by counsel, yes?
A. Yes.
Q. All right. And you understand from that that Mr. Legg measured particles using a handheld particle counter called a HandiLaz, correct?
A. Correct.
Q. And that that particle counter was positioned 10 centimetres over the surgical site, correct?
A. Yes.
Q. And you understand from your review of that material that there was an increase in temperature when the forced air warming was used, correct?
A. My understanding was that was an

Page 298

increase of about 1.1 Celsius.
Q. All right. And you understand that the authors also reported a considerable increase in the number of smaller-sized particles, correct?
A. Yes. My understanding was the largest increase was in the .3 micron size.
Q. Okay. And do you have an opinion, as you sit here today, about what size particle is necessary to transmit an airborne pathogen?
A. My understanding is the bacteria that is of concern is larger than the .3 micron size, and the .3 micron size is not representative in referencing what we looked at earlier in the chart of particle sizes and the fact that the particles are often either clumped together or attached to other larger particles, that the particle size in question here would be larger than that .3 micron size; in fact, likely, in most cases, larger than the 1 micron size. And, therefore, the .3 micron size was not representative of that bacteria of concern.
Q. Okay. So there is a lot in your answer right there. When you are referring to the charts that we just walked through, those are the Kowalski charts that are depicted at Figure 11 in your report; is that right?

Page 299

A. That is correct.
Q. And that lists out the size in micrometres of various viruses and bacteria; is that right?
A. That is correct.
Q. And you would agree that, at least the staphylococcus aureus...are you aware that that is a bacteria?
A. Yes.
Q. All right. And the Kowalski chart that you cited in your report lists that as a .866 micrometre size, correct?
A. Yes.
Q. All right. And there are some additional bacteria that are listed in this Kowalski chart, but just, as it is getting to be a long day, we won't go through every one of the bacteria; is that fair? What is your basis for saying that the bacteria travel in clumps?
A. That is through my experience in understanding how the bacteria travels, and in also my review of the documentation that I reviewed as part of this case.
Q. All right. Do you know how many bacteria or pathogens it takes to cause a surgical

Page 300

site infection?
A. No.
Q. Could it be as low as one colony-forming unit?
MR. GOSS: Objection, lack of foundation.
THE DEPONENT: I would defer to a...I would defer to an epidemiologist, microbiologist on the number of particles.

BY MS. ZIMMERMAN:
Q. Okay. At any rate, you are not going to be offering any testimony at trial in this matter about how many particles is required?
A. That is correct.
Q. All right. Or how many pathogens, I should say.
MR. GOSS: You can answer that one.
THE DEPONENT: Sorry, no, I won't be.

BY MS. ZIMMERMAN:
Q. All right. So you characterize the change in particle counts of 5.0 micrometre size as negligible in the Legg 2012 report; is that right?
A. I actually just, I believe, reported what Legg reported as a negligible change in particle

Page 301

size at the 5 micron level.
Q. All right. And, at the end of the day, your characterization of the Legg article is that Legg does not show a meaningful increase in particles of the 5.0 micrometre size when Bair Hugger is on; is that right?
A. That is what I got from his study, yes.
Q. Okay. And then you cite to the Sessler study in 2011, and that was provided to you by counsel as well, correct?
A. Yes.
Q. And the second author on that article is R.N. Olmsted. You understand that to be Russ Olmsted?
A. Yes.
Q. And you have met Russ Olmsted before?
A. Yes, I have.
Q. Where did you meet him?
A. At ASHRAE meetings.
Q. All right. And have you worked with him?
A. I have worked with him on ASHRAE matters.
Q. Okay. How many times?

A. I don't recall. He has been on the committee for a number of years and so have I.
Q. Would you consider him a friend of yours?
A. No.
Q. All right. And he is one of the authors on the Sessler paper, correct?
A. Yes, he is.
Q. All right. And have you ever discussed the Bair Hugger matters with Mr. Olmsted?
A. No, I haven't.
Q. Have you been provided the depositions of either Dr. Sessler or Mr. Olmsted in this matter?
A. Can you repeat the question, please?
Q. I will try. Have you been provided depositions of either Dr. Sessler or Mr. Olmsted in connection with this case?
A. No, I haven't.
Q. Do you think that reading their depositions may provide some relevant information as you consider your opinions with respect to their study?
MR. GOSS: Object to form.
THE DEPONENT: I would have to look at

them to determine whether they would have any influence on my opinions.

BY MS. ZIMMERMAN:
Q. All right. And, as you sit here right now, you don't know if their depositions have an opinion on your...have an impact on your opinion, because you have never seen them, right?
A. I don't know what is in their depositions.
Q. All right. And you weren't provided those depositions by counsel, correct?
A. I was not provided those.
Q. All right. And do you have anything critical to say about this Sessler study?
A. In my report, I translated their findings about no significant increase in particles of the size they measured when the forced air warming was turned on, but I had nothing else that I brought into my report as an opinion.
Q. And it says in your report, and I am guessing this is a typo:
"...Sessler studied particle counts also at 10 centimetres..."
Okay. Ten centimetres over the surgical site. And

the range, again, is .5 to 1 micrometre, correct?
A. That is what it says, yes.
Q. Okay. Did you look at any of the raw data underlying Dr. Sessler's studies?
A. I read the report as published.
Q. You read the report as published but none of the underlying raw data, correct?
A. I did not look at any other data that was not included in the report.
Q. All right. And you haven't been provided the videos that were taken in connection with that study, have you?
A. Again, because I have difficulty correlating videos I saw to the reports, I don't know whether I saw that. I don't have a copy of it, of the video. And so I can't recall whether any of the videos I saw were related to this report or not.
Q. Okay. Moving on to Mr. McGovern. I guess he is back Dr. McGovern. They go back and forth in the U.K., apparently, based on whether... what level of education or what your specialty is. Mister is more advanced than Doctor, and I cannot get my head around it. So, the Dr. McGovern study in 2009, and that is cited as reference (u). So that was provided to you by counsel, correct?

A. Yes, it was.
Q. And the title of that article is "Do forced air warming devices increase bacterial contamination of operative field? - Simulated experiment analysis", correct?
A. Yes.
Q. And that is in 2009, right?
A. Yes.
Q. And your criticism, as I understand it, of Dr. McGovern's study is that the increase in particle counts perhaps is only attributable to when the surgeon entered the operative field; is that right?
A. He measured no notable increase of particle count when the forced air warming device was used, and that the increase that he noticed was only when the surgeon entered the operative field.
Q. Okay. And then we spoke a little bit earlier about Memarzadeh, 2010, right?
A. Yes.
Q. Now, moving on to page 17, you talk about the thermal plume as a protective barrier. And you understand that Dr. Memarzadeh is a proponent of the thermal plume theory, correct?
A. Yes.

Page 306

Q. And I think that you agreed earlier that protecting...creating that protective cocoon around the surgical site is important, correct?
A. Yes.
Q. And, in your opinion, it would be a bad idea to do anything to disrupt that protective cocoon around the surgical site, correct?
MR. GOSS: Object to form.
THE DEPONENT: Yes. I have difficulty with your terms of "disrupting that protective cocoon". Part of the disruption of the buoyant plume on the laminar flow as described in this section is actually what helps create that protective cocoon.

BY MS. ZIMMERMAN:
Q. The laminar flow creates a protective cocoon?
A. The disruption of that laminar flow by the thermal plume is what helps create that cocoon, protective cocoon itself.
Q. Okay. So you believe that the heat rising from the surgical site is disrupting the laminar flow and creating the thermal plume?
A. And creating a cocoon, yes.

Page 307

Q. And creating a cocoon. Okay. In any event, you would not think it is prudent to have a laminar flow system that was sufficiently powerful to overcome that protective cocoon, correct?
A. Correct.
Q. As you sit here today, besides Memarzadeh...and by the way, with the thermal plume section that is listed as subsection d), there's no citations to this. I see that this Figure 12 and 13, as I understand it, are your drawings to visualize the effect of this thermal plume, or the protective cocoon, as you call it. Are you aware of any scientific peer-reviewed evidence to support this thermal plume theory, besides Memarzadeh?
A. Besides Memarzadeh?
Q. Yes.
A. No, I am not.
Q. And have you heard others criticize the thermal plume theory in the past?
A. Yes, I have.
Q. And have you personally ever calculated the buoyancy or the force of this protective cocoon, or this thermal plume, however you describe it?
A. I have not done personal calculations

Page 308

on that.
Q. Do you know if anyone else has?
A. I know that Farhad Memarzadeh has.
Q. At any rate, you haven't done that in connection with this case, correct?
A. I have not done the calculations, no.
Q. All right. And you're not going to be offering any testimony in court or trial at this matter about the forces involved in the thermal plume and the protective cocoon?
MR. GOSS: Object to form.

BY MS. ZIMMERMAN:
Q. Are you going to be doing the calculations...
MR. GOSS: Okay. That...
THE DEPONENT: It's a different question, yes.

BY MS. ZIMMERMAN:
Q. Have you been asked to do the calculations?
A. No. You asked two different questions there. I am not going to be testifying on any calculations on the thermal plume, but I am

Page 309

providing opinion on the thermal plume, yes.
Q. All right. And, to your knowledge, the only person who has published in a peer-reviewed journal on the thermal plume theory is Dr. Memarzadeh, correct?
A. That is the only one that I am relying on, yes.
Q. All right. And Dr. Memarzadeh has, in fact, himself conducted or performed the mathematical calculations to represent the forces of this thermal plume, correct?
A. Yes.
Q. And that is not a calculation that you have done at this point in this case, correct?
A. I have not done that calculation.
Q. Okay. Have you been asked to do that calculation?
A. I have not been asked to do that calculation.
Q. All right. Turning to the Settles report, which I think you cite at number (w)...letter (w), not number (w)...that was another one that was provided to you by counsel, I presume?
A. Yes, it was.
Q. All right. And you understand that

Page 310

that is not a peer-reviewed publication; that is a report that was generated to advance 3M's defence in this Bair Hugger litigation, correct?
A. I only understand that it is not peer-reviewed as you have told me today.
Q. Okay. And you understand the purpose for Settles rendering that report?
A. I understand the scope and content of what he has done in that report, and I have reviewed that report to help inform my report.
Q. Okay. And I assume that you haven't seen, you know, any of the billing or invoices that have been associated with that report, correct?
A. I have not seen any of the invoices related to that.
Q. Okay. And, to your knowledge, the report generated by Settles has not been submitted for publication or anything to that effect, correct?
A. I am not aware.
Q. And, at any rate, back at, I think, the earlier part of today, we talked about Settles using the Schlieren imaging technique, and you said you had some familiarity with that at one point; is that right?
A. Yes.

Page 311

Q. And is that something that you learned about in undergraduate work?
A. No.
Q. All right. When did you learn about it?
A. I learned about that during the course of this case.
Q. Did you...who did you learn about it from?
A. The Schlieren imaging?
Q. Yes.
A. I read it from Settles' report, for one.
Q. Okay. Is your understanding of the Schlieren imaging technique limited to what is contained in the Settles report?
A. I can't recall now if there were any other documents that I referred to that dealt with the Schlieren. If there were, then that would be part of it. Otherwise, it is primarily based on this.
Q. Okay. And, at any rate, prior to being engaged in this particular case, you had no experience with the Schlieren imaging technique, did you?

Page 312

A. I find that one difficult to answer, actually, because I have seen images consistent with what is shown in the Schlieren images of Settles' report. But, in the past, I would have not recognized them as a Schlieren image, so perhaps they were. But I definitely...I have seen heat emanating images before like that.
Q. All right. And...
A. So whether they were Schlieren or not, I couldn't tell you at this time.
Q. Okay. And you were provided with the deposition of Professor Kuehn taken just this past Monday, correct?
A. I was.
Q. And so you did read at least some portion of that deposition?
A. I did read a portion of it.
Q. All right. And so then you know from Professor Kuehn's testimony then that the last time he used Schlieren testing was during his PhD thesis work 40 years ago, right?
A. I don't recall that, but I will take it as you state it.
Q. Okay. But, in any event, you are not aware of anything that would represent that the

Page 313

Schlieren imaging technique is a modern, cutting-edge way of measuring these kinds of heat?
A. I am not in a position to comment on that.
Q. Okay. And you're not going to be offering any opinion about whether or not Settles has used the technique correctly, right?
A. Correct.
Q. You will defer to him on that?
A. Yes.
Q. Do you know, as you sit here right now, what temperature the air is when it leaves the Bair Hugger device?
A. I have seen a number of different references to temperature on the Bair Hugger, and so I could not say definitively what the exact temperature would be.
Q. All right. And that is not anything that you have personally measured, at any rate?
A. I have not personally measured it.
Q. All right. Moving to section e), "Attempts to use particle counting to predict bacterial contamination". You explain that "there are several studies that propose that microbiological air quality in the operating theatre can be

Page 314

indirectly evaluated by means of particle counting, a technique derived from the industrial clean-room technology standards, using airborne particle concentration as an index of microbial contamination". Did I read that right? I hope I did. And then you cite to (x) as an endnote, and then there is, in brackets, "(Landrin 2005)", L-A-N-D-R-I-N 2005?

A. Yes.

Q. Is that an additional citation that you intended to have in your list of references, or did I...perhaps I missed...

A. So, in my drafting of the report, before I built my list of references at the back of the report, I would include brackets after paragraph to indicate the reference to remind myself to go back and put a reference in the report.

Q. Okay.

A. So this leads me to believe that I was referring to Landrin, although it somehow did not make it into the reference listing at the back.

Q. All right.

A. But I also have a reference to (x), which is a Cristina document, which is in the reference document. So I can't tell you for sure

Page 315

what I intended to do, whether both needed to be referenced or if it was only one and the other one wasn't, and that this was part of the report. I couldn't tell you right now. It was an omission of mine to clarify the reference in here.

Q. Okay. I appreciate that. In any event, this Landrin article from 2005 seems to be something that you considered in forming your opinions that you reflect in your report; is that right?

A. I don't recall...sorry, I would have considered it. Whether it actually was a basis for any of the opinions in this section, I don't recall at this time.

Q. Okay. And (x), at any rate, the Maria Luisa Cristina article, "Can particulate air sample predict microbial load in operating theatres for arthroplasty?", that was one of the articles that was, in fact, produced to you or provided to you by counsel, correct?

A. Correct.

Q. All right. And, again, while you have a section about appropriate or...about the use of particle counting to predict bacterial contamination, actually doing particle counting is

Page 316

not something that you personally do, correct?

A. I have initiated particle counting studies in my role, but I have not done any actual particle counting myself.

Q. Okay. And that is not something that you are trained to do?

A. I am not trained to do that.

Q. Okay. Yet you offer opinions about interpretation of particle counting, correct?

A. Yes.

MS. ZIMMERMAN: Mr. Keen, I am showing you now what has been marked as Exhibit 11 to your deposition today.

--- EXHIBIT NO. 11: Article by Birgand et al., from the American Journal of Infection Control, 2015

BY MS. ZIMMERMAN:

Q. Do you recognize this article? And if it would help, given the time of day, I think it may be...

A. Reference (i).

Q. ...reference (i).

A. Yes, I do recognize this article.

Page 317

Q. Okay. And it seems, based on the discussion earlier, you weren't sure if this was an article that was produced to you by counsel or one that you found on your own in researching issues related to this case; is that right?

A. That is correct.

Q. Okay. And if I represent to you that this article is only available for purchase, does that help in any way in identifying whether this may have been produced by counsel or something that you personally purchased in your preparation for this matter?

A. No. Sadly, it does not help.

Q. Okay. If you purchased an article, would it appear on the invoices that you submit to counsel?

A. I did not purchase any articles.

Q. Okay. So if you didn't purchase the article, it probably came from counsel; does that seem fair?

A. I wouldn't come to that conclusion.

Q. Okay.

A. I found a number of articles for purchase on the internet.

Q. Okay. At any rate, is this an

article that you had become familiar with prior to your involvement in this case, or did you just become aware of it in connection with your retention in this case?

A. I became aware of it with this case only.

Q. All right. And do you know what the authors of this particular study ultimately conclude with respect to predicting...pardon me, with respect to use of particle count to predict air microbial counts?

A. Off the top of my head, I am not recalling right now. I would have to look at it again.

Q. Okay. And so I will steer you to the last page of the article, right before the acknowledgment section, the paragraph starts out:

"...We found a strong correlation between air particle counts and microbial contamination, suggesting that particle counting can be used for routine evaluation of contamination in the OR ventilated with turbulent airflow or LAF [laminar airflow]..."

Correct?

A. That is what it says, yes.

Q. All right. And this is one of the articles that you cited in your report as authoritative, correct?

A. It was one of the articles that I cited for a different purpose in the report.

Q. Correct. You cited it for a different purpose, correct?

A. That is correct.

Q. All right. And if you jump ahead to page 23 of your report, subpart e), one of the seven opinions that you are prepared to offer to the court in this matter listed at letter e) is that "particle count is not a good surrogate for bacterial count", correct?

A. Correct.

Q. And that would be directly at odds with the conclusions reached by Birgand, as outlined in Exhibit 11, correct?

A. No, I wouldn't say that. I would say that they said that, on this study, they found a correlation between air particle counts and microbial contamination. And that my statement of it not being a good surrogate is not necessarily inconsistent with that.

Q. So the Birgand authors say, "We found a strong correlation between particle counts and microbial contamination, suggesting particle counting can be used for routine evaluation of contamination in the OR ventilated with turbulent airflow or LAF." Your opinion in letter e) is "particle count is not a good surrogate for bacterial count".

A. That is correct.

Q. And you find those to be not in conflict with one another?

A. That is correct.

Q. Okay.

A. I would say that the...as I talk about in my report, that possibility of a correlation could happen, but that it's not necessarily the case, especially in the positive. In the negative side, in the decrease of particles would indicate a decreased risk. However, an increase doesn't necessarily...an increase in particle count doesn't necessarily result in a correlated increase of microbial contamination, although that could happen.

Q. Well, isn't, though, what these authors find directly in contrast to that...what is the P-value of the findings...or, pardon me, of the results in the Birgand article with respect to this

question?

A. I would have to go back and analyze that.

Q. All right. And it is right in front of you in the article.

A. Can you point me to that P-value, if you have a reference?

Q. Sure. So, "particle sizes and a turbulent ventilation system were associated with an increased number of air microbial counts".

A. I am sorry, where are you reading from?

Q. The very last line of "Results" section on the first page.

MR. GOSS: If you need to take a minute to review this.

BY MS. ZIMMERMAN:

Q. So do you see the last sentence there that associates the particle sizes in a turbulent ventilation system being associated with an increased number of air microbial counts, and the authors provide a P-value of less than .001 percent?

A. Yes, I see that.

Q. Okay. And you still disagree that

Page 322

your opinion offered in letter e) is in contrast with that conclusion?
A. I would say that the generality of, taking beyond this study, that particle count could be a surrogate for microbial contamination should not be extended, and I would continue to support my statement that it is not a good surrogate.
Q. Okay. Jumping ahead to the other conclusions of summaries of your opinions offered on pages 22 and 23, at letter a), you are prepared to opine to the court in this case that, given that the Bair Hugger unit contains an intake filter, which you believe is tested to perform at a MERV 14 rating, that that would be effective at controlling airborne bacteria; is that right?
A. Yes.
Q. And from there you also extrapolate or opine that the ASHRAE standard of 170, which requires a MERV 14 filtration on supply air, would also be an appropriate filter to include on the unit; is that right?
A. Yes.
Q. And you would agree that ASHRAE standards do not apply to medical devices, correct?
A. I would agree.

Page 323

Q. All right. And you would agree that you have no experience personally in designing medical devices, correct?
A. That is correct.
Q. All right. And the opinion that you are preparing to offer is that ASHRAE should govern appropriate filter selection for a medical device, correct?
MR. GOSS: Objection to form.
THE DEPONENT: That is not the opinion I am providing in the report.

BY MS. ZIMMERMAN:
Q. What is the opinion you are providing?
A. The opinion I am providing is that the Bair Hugger has a filter that performs at a MERV 14 rating, and I am saying that that MERV 14 filtration is appropriate, since the air supply to the room is done at a MERV 14 rating.
Q. All right. But you agree that ASHRAE standards with respect to HVAC systems are not the same...do not govern medical devices, correct?
A. As I mentioned earlier, I am not aware of a standard for filtration of medical

Page 324

devices.
Q. All right. You're not aware of a standard for filtration of medical devices, and you have no experience in designing filters for medical devices, correct?
A. That is correct.
Q. And you have no experience in evaluating filters for medical devices, correct?
A. No. I have experience in interpreting the rating of filters under the ASHRAE 52.2 method, and so...and interpreting the results of an ASHRAE 52.2 test.
Q. Is it your testimony that ASHRAE 52.2 governs filters on medical devices?
A. No. It is my testimony that the filter in this case was measured to the standard of ASHRAE 52.2 testing.
Q. All right. And before today, you were not aware that other forced air warming products use MERV filtration, correct?
A. That is correct.
Q. All right. But, at any rate, you have not personally designed a medical device before, ever, correct?
A. I have not.

Page 325

Q. All right. And, to your knowledge, ASHRAE standards on filtration have not been applied to medical devices, correct?
A. No. To my understanding, ASHRAE tests of the ASHRAE 52.2 have been applied to test filters in medical devices, such as the filter in the Bair Hugger, which was tested to that standard.
Q. Pursuant to a MERV rating or pursuant to an ASHRAE standard?
A. Pursuant to the test procedure within ASHRAE 52.2, which then correlates to a MERV rating.
Q. Right. But ASHRAE 52.2 governs the efficiency of the filter, correct?
A. ASHRAE 52.2 provides a test procedure for evaluating the filter.
Q. Okay. What other medical devices, besides the Bair Hugger, do you believe have been governed by ASHRAE 52.2?
A. I am not aware of any medical device that is governed by a standard for requiring filters.
Q. Okay. And yet you have outlined and are prepared to offer the opinion that ASHRAE 170 and ASHRAE 52.2 govern the Bair Hugger in some manner?
A. No, I have not offered that opinion.
Q. The summary of your opinion is that

the ASHRAE Standard 170 requires a MERV filtration on supply air in the HVAC system?

A. That is correct.

Q. And if I am understanding correctly, because it is good enough for the HVAC system, it must be good enough for a medical device in the OR; is that right?

A. That is my opinion.

Q. And that is the summary of your opinion?

A. Yes.

Q. All right. Are you aware of ASHRAE weighing in on whether or not that is appropriate for medical devices as well?

A. I am not aware of ASHRAE weighing in on the appropriateness of a MERV 14 filter for a medical device.

Q. The second opinion that you offer has to do with laminar flow characteristic in an operating room. You note that:

"...[It] is an important design feature to provide a protective field from infiltration of possible contamination..."

You then say:

"...However, it should be recognized that

there are many sources of heat generation and physical obstruction typically within the laminar airflow field that disrupt it and can cause some turbulence..."

And you have agreed with me today that one of those things may well be the Bair Hugger, correct?

A. Correct.

Q. It is then your opinion that:

"...Bubbles are not a reliable simulation for particle movement in an operating room..."

Is that right?

A. That is correct.

Q. All right. And with respect to issues of particle physics, you are going to defer to an expert in particle physics, correct?

A. Yes.

Q. All right. In letter f), you note that:

"...Some studies have found positive bacteria swabs in the outlet hose of the Bair Hugger..."

But you say:

"...However, bacterial contamination has not been demonstrated to propagate into the

operating room when used as recommended attached to a blanket. It has also been shown that the level of contamination inside the hose is relatively clean and not as significant as the contamination of frequent touch points in the operating room..."

What is the basis for this opinion?

A. There are a number of different articles that I reference in my report that led to this opinion, including studies where the hoses were swabbed for bacterial contamination, and then, again, whether that bacterial contamination was demonstrated to propagate outside of the blanket, as I mention in studies again that have been referenced in my report. There were also other studies involving bioluminescence that showed that the contamination inside the hose was relatively clean compared to a number of different contamination points within the operating room.

Q. Okay. Can you name, as you sit here, which studies you refer to with respect to this positive bacterial swabs?

A. I believe the reference to the positive bacterial swabs was referred to from Avidan.

Q. All right. Anyone besides Avidan?

A. Albrecht.

Q. And have you been provided any internal company documents that confirm that...

A. Sorry, can you give me one second?

Q. Sure.

A. I believe that is all, to answer that question previously.

Q. Okay. So, Avidan and Albrecht?

A. Yes.

Q. All right. And have you been provided any internal company documents from Arizant or from 3M that address this issue of positive bacteria swabs?

A. No, I have not.

Q. All right. Have you seen any of the internal company testimony that concede that these devices are frequently found to be contaminated?

A. No...

MR. GOSS: Object to form.

THE DEPONENT: No, I have not.

BY MS. ZIMMERMAN:

Q. And have you seen any of the studies that reflect that the inside of the Bair Hugger hose is a particularly hospitable place for bacteria to

Page 330

grow?
MR. GOSS: Object to form.
THE DEPONENT: Other than the studies I have mentioned to you, I have not...and I don't recall if they actually made that comment, so I don't recall anything else that made that claim, and I don't think those studies that you did, to be honest.

BY MS. ZIMMERMAN:
Q. All right. So, in your role at a hospital here in Ontario, can you imagine a situation where an orthopaedic surgeon would consent to having a device in the operating room that harbours colony-forming units of bacteria?
MR. GOSS: Object to form, lack of foundation.
THE DEPONENT: I find that kind of speculative, and I am not sure what you are asking there.

BY MS. ZIMMERMAN:
Q. Right. I am asking you to assume that a device is known to be contaminated or known to host colony-forming units of bacteria. Can you

Page 331

imagine any orthopaedic surgeon who would allow that device to be in their operating room for an orthopaedic surgery?
MR. GOSS: Object to form, lacks foundation, beyond his expertise.
THE DEPONENT: Yes. I am not an orthopaedic surgeon, so I wouldn't want to guess at what they would say.

BY MS. ZIMMERMAN:
Q. In your role as an engineer who takes patient safety as a paramount consideration, would you knowingly allow a device to be in an operating room at your hospital that you knew to have colony-forming units of bacteria in it?
A. I know that, as a general point, there are...despite the best efforts of systems and people, that there are colony-forming units that exist in an operating room. And so, I would have to understand better whether or not a discovery of colony-forming units in an item posed a risk that I thought was likely, given the circumstance.
Q. All right. And that is really not my question, though. If you know what device has colony-forming units inside the device and you...in

Page 332

your role as a manager at a hospital concerned about patient safety, would you allow that device to be in the operating room during an orthopaedic surgery?
MR. GOSS: Object to form, asked and answered.
THE DEPONENT: Again, I would have to look at the specific case, because, again, I know that there are colony-forming units that exist in every operating room.

BY MS. ZIMMERMAN:
Q. And you know from your work with ASHRAE and with other Canadian counterparts that the intention is to clear any...to make the room as...achieve asepsis, if possible, correct?
A. The objective is to achieve asepsis, yes.
Q. Right. And achieving asepsis is going to be impossible if a machine is known to have colony-forming units of bacteria in it, correct?
MR. GOSS: Object to form.
THE DEPONENT: As answered previously, achievement of total asepsis, I am not aware that that is possible. And so, the risk of any individual potential contamination would

Page 333

have to be evaluated.

BY MS. ZIMMERMAN:
Q. We had some questions early on about ethical practice and engineering standards here in Ontario. Do you remember that?
A. Yes, I do.
Q. And you agreed that good ethical practice should govern engineers for corporations as well, correct?
A. Yes.
Q. All right. And would you agree that good engineering ethics would require an engineer to listen to complaints of potential problems?
MR. GOSS: I am just going to restate my continuing objection to ethics. You can answer.
THE DEPONENT: Yes, I would.

BY MS. ZIMMERMAN:
Q. All right. And I am going to ask you to assume that some of the key opinion leaders for 3M Company have repeatedly urged the company do studies about the risk of infection connected with the Bair Hugger machine. Do you think that refusing

Page 334

to do those studies is good engineering practice?
MR. GOSS: Objection, assumes facts not in evidence, beyond the scope of his opinions in this case.
MS. ZIMMERMAN: You can answer.
THE DEPONENT: I can't comment on the decision-making process of what studies are being conducted by 3M.

BY MS. ZIMMERMAN:
Q. Okay. And have you been provided any documents that show that the intention of 3M employees was to prevent independent organizations from doing their own studies?
A. No, I have not.
Q. And would seeing documents that confirm that kind of an intention impact the opinions you have rendered in connection with your retention in this case?
MR. GOSS: Objection, calls for speculation, outside the scope of his report opinions. You can answer.
THE DEPONENT: Again, I wouldn't speculate as to the decision-making process of what studies they would be doing based on

Page 335

information.

BY MS. ZIMMERMAN:
Q. All right. And in your...as you prepared for and reviewed materials to write the report that you drafted in this case, you relied on counsel for 3M to provide you all the materials that you would need to reach complete and reliable opinions, correct?
MR. GOSS: Object to form.
THE DEPONENT: As I have already answered, I relied on them for some of the materials they provided, and I also found some of my own materials.

BY MS. ZIMMERMAN:
Q. All right. And for those materials that they did provide, you relied on counsel for 3M to make sure that that production was complete, correct?
MR. GOSS: Objection to form.
THE DEPONENT: I was asked to look at a scope for my report in response to a number of questions, and based on the number of articles I was provided. And so, I provided

Page 336

my opinions based on that list of questions and the reports provided and some of my own independent research.

BY MS. ZIMMERMAN:
Q. All right. And you would agree that those opinions may change, they may not change, if you were provided additional information in this case, correct?
MR. GOSS: Calls for speculation.
THE DEPONENT: In fact, I would quote from my report that I said that these opinions are held to a reasonable degree based on the information that was presented. And that I reserve the right to amend or supplement my report and opinions if I had any additional information or context.

BY MS. ZIMMERMAN:
Q. Yes, I see that. But, as you may know, or maybe you don't know, discovery with respect to general causation in this case has concluded, which means that we are in a different phase of the case and we're not going to be learning anything more at this time about general issues about how the

Page 337

machine works and what kind of scientific testing has been done about it at this point; do you know that?
A. As I stated before, I am not aware of the legal process for how that plays out. All I am saying is that if I received additional information that impacted my opinion, it may change my opinion.
Q. Okay. With respect...and, again, you may not know the phases of the case. We are now in what we call specific causation discovery. As you sit here today, is there anything that you can anticipate on...that you might learn from one particular patient's medical records that would impact the opinions you've offered so far in this matter?
A. I would have to review that information to see whether it had an impact on my opinions.
MS. ZIMMERMAN: Okay. At this point, pending production of some of the additional...I want to mark the documents that the witness brought with him. And then, pending receipt of a complete production, both of documents cited and of documents produced to counsel that were responsive to our subpoena, we will leave

the deposition open on those issues. And also, with respect to the videos, if we can get identification of what videos have been relied upon. And, other than that, I think that you've got time to make your train.

--- EXHIBIT NO. 12: Bundle of documents supplied by Michael Keen

RE-EXAMINATION BY MR. GOSS:

Q. I guess I just have one question relating to the videos, because, as I hear your testimony, I am not totally sure that I understand all the videos. But are there any opinions in your report that stand or fall based on your review of a video?

A. No. The videos were mainly, as I stated earlier, visualizations of information that I had already used for my opinions. And, based on that visualization and the production of the video, it did not change my opinion stated.

MR. GOSS: That is it.

--- upon adjourning at 6:37 p.m.

1 United States District Court subpoena to Michael Keen, c/o Blackwell Burke, dated June 7, 2017 8
2 Curriculum vitae of Michael Keen 24
3 E-mails between Michael Keen and Catherine Hogan, dated April 21, 2017 37
4 Fragment of LinkedIn correspondence between Michael Keen and Dan Koenigshofer, dated April 17 and April 26, 2017 41
5 Expert report of Michael Keen, dated June 2, 2017 50
6 Printout from the website of Professional Engineers Ontario, re code of ethics 67
7 Image of Bair Hugger 200 series machine, showing sign titled "Important Notes" 83
8 Image of Bair Hugger 200 series machine warning label 84
9 Expert report of Dan Koenigshofer, dated March 31, 2017 239
10 Letter to the Editor, written by Dr. Memarzadeh, submitted to the Journal of Hospital Infection, 2010 272
11 Article by Birgand et al., from the American Journal of Infection Control, 2015 316
12 Bundle of documents supplied by

M. Keen

I hereby certify the foregoing to be a true and accurate transcription of the above noted proceedings held before me on the 14th DAY OF JULY, 2017 and taken to the best of my skill, ability and understanding.

} Certified Correct:

} ___________________________

} Sarah Melse

} Certified Verbatim Reporter

M. Keen

ERRATA SHEET

PAGE	LINE
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....
....	....

I, MICHAEL KEEN, have read and reviewed pages 3 to 338 and, with the exception of the above-noted corrections, hereby agree to the accuracy of my statements recorded herein.

Date Michael Keen

EXHIBIT DX2

TO DECLARATION OF MONICA L. DAVIES IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF MICHAEL KEEN, P.ENG., MBA

KOENIGSHOFER

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLN)

VIDEOTAPED DEPOSITION DANIEL KOENIGSHOFER, P.E.

Chapel Hill, North Carolina

June 13, 2017

Randi J. Garcia, RPR

Job no. 124784

KOENIGSHOFER

system for an operating room -- for -- should be higher than 14?

A. Not for a general operating room.

Q. What about other than for a general operating room?

A. I have suggested that maybe we should start requiring it for orthopedic operating rooms.

Q. And you suggested this during a committee meeting of -- of the 170 Committee?

A. Yes.

Q. Did you make that recommendation -- when do you recall making that recommendation?

A. As Jim said, I've been going to these meetings for 14 years, two or three a year for 14 years. I honestly can't remember at what point.

Q. Was it in the last two years?

A. I would say probably before that.

Q. Has it been your experience that orthopedic rooms sometimes do incorporate HEPA filters?

A. Yes.

Q. And nothing in this table would

KOENIGSHOFER

prevent an orthopedic room from doing that; correct?

A. That's correct.

Q. In your -- in the various meetings you've attended for Standard 170, do you have any understanding as to whether the committee intends to increase the minimum filter requirements for Class B and Class C surgery?

MS. ZIMMERMAN: Object to form.

THE WITNESS: Among the addenda on the table at this time, that is not one of them.

BY MR. GOSS:

Q. Where it says "Class B and Class C surgery," am I correct that orthopedic surgery would be encompassed within one of those classes?

A. Yes.

Q. Which one is it?

A. It's probably the Class C, I would assume.

Q. And the only space designation on this table 6.4 that calls for HEPA is a protective environment room; correct?

KOENIGSHOFER

A. That's correct.

Q. And this protective environment room, is that where you put someone who is contagious with a respiratory illness, for example?

A. No, just the opposite.

Q. It's where you put somebody who's susceptible that you need to protect?

A. Correct.

Q. Okay. Are the HEPA filters in protective environment rooms, are they on the inflow to the room or the outflow from the room?

A. Inflow.

Q. If you'll turn with me to page 14, section 7.4 talks about surgery rooms. And if you look at point A, it says, "The airflow shall be unidirectional downwards and average velocity of the diffuser shall be 25 to 35 cubic feet per minute per square foot."

Are you familiar with that requirement for the face velocity or volume metric flow out of the diffusers?

A. Yes.

Q. And it says here, "For further

KOENIGSHOFER

information, see Memarzadeh and Manning 2002, and Memarzadeh and Jeong in informative appendix B." Are you familiar with the Memarzadeh and Manning paper on this subject?

A. Yes.

Q. So what is -- what is the reason that Memarzadeh and Manning gave for setting the airflow volume and velocity at 25 to 35 CFMs per square foot?

A. Well, it was to get adequate air changes, 20 per square foot -- I'm sorry, 20 air changes per hour. And given the size the laminar diffuser is going to be, roughly the size of the table plus a foot or two on each side, you have to have a certain amount of airflow to get those air changes.

Q. Okay. But is there something about this particular velocity that's important, the 25 to 35 CFMs?

A. Memarzadeh hypothesized about a wound plume.

Q. Tell me about that. What does he mean by "wound plume"?

MS. ZIMMERMAN: Object to form.

KOENIGSHOFER

Foundation. You can answer if you know.

THE WITNESS: My understanding is that he felt like there's a small amount of heat coming off of an exposed part of the body, which would cause a convective updraft and that little thermal mushroom cloud would contain only the bugs from that patient. And, therefore, you do not want your velocity from your diffusers to be so great that it blows away that wound plume.

BY MR. GOSS:

Q. So Memarzadeh and Manning, did their research involve computational fluid dynamics, if you know?

A. Yes.

Q. You're familiar with the paper from 2002?

A. Yes.

Q. And the wound plume, as you described it, has a protective effect for surgical site infection. Isn't that what's hypothesized, at least, in the article?

A. Yes.

KOENIGSHOFER

Q. Do you believe that to be true?

A. I am skeptical that the temperature of the wound would be sufficient to cause much of a mushroom cloud.

Q. But if it did cause a slight thermal updraft, is it your opinion that that would be protective for purposes of preventing surgical site infections?

A. Yes.

Q. And so the point of limiting the velocity of the diffusers to 35 CFMs -- I may have -- I may have my units wrong. Is it feet per minute?

A. We are talking feet per minute velocity.

Q. Feet per minute is velocity. Okay. So the whole idea behind limiting the velocity to 35 feet per minute is to avoid overcoming whatever protective updraft may be coming from the patient; is that correct?

MS. ZIMMERMAN: Object to form. Foundation.

THE WITNESS: Say it again.

KOENIGSHOFER

BY MR. GOSS:

Q. The reason for limiting the velocity to 35 feet per minute is to avoid disrupting the protective plume on the patient, or do you know?

A. It is my understanding that is Memarzadeh's thinking.

Q. Is that how you pronounce it? Thank you. I didn't know.

A. Yes.

Q. Memarzadeh. I'm glad to know that.

MS. ZIMMERMAN: I've been saying it wrong the whole time.

BY MR. GOSS:

Q. I was saying it like marmalade.

A. Pretty much all of us just call him Farhad.

Q. Farhad. Okay.

A. It's a lot easier.

Q. All right. And Memarzadeh's thinking has been incorporated into Standard 170 by limiting the velocity of the diffusers to 35 feet per minute; correct?

MS. ZIMMERMAN: Objection to form.

KOENIGSHOFER

Foundation.

THE WITNESS: That is my understanding. That was written before I was on the committee.

BY MR. GOSS:

Q. Okay. But obviously they're citing his paper right here where they talk about the diffuser shall be 25 to 35 feet per minute; correct?

A. Yes.

MS. ZIMMERMAN: We've been going about an hour.

BY MR. GOSS:

Q. Let me take a quick look here. This might be a pretty good place to stop.

The only other thing I was going to ask you about in this section. So we talked about how you may have or you contributed to some addenda for Standard 170; correct?

A. Well, I've contributed in -- I don't know that a word that I have written has been in there. But, I mean, I've deleted words and changed some things. These things go around the table many times.

EXHIBIT DX3

TO DECLARATION OF MONICA L. DAVIES IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF MICHAEL KEEN, P.ENG., MBA

STANDARD

ANSI/ASHRAE/ASHE Standard 170-2013
(Supersedes ANSI/ASHRAE/ASHE Standard 170-2008)
Includes ANSI/ASHRAE/ASHE addenda listed in Appendix C

Ventilation of Health Care Facilities

See Appendix C for approval dates by the ASHRAE Standards Committee, the ASHRAE Board of Directors, the ASHE Board of Directors, and the American National Standards Institute.

This standard is under continuous maintenance by a Standing Standard Project Committee (SSPC) for which the Standards Committee has established a documented program for regular publication of addenda or revisions, including procedures for timely, documented, consensus action on requests for change to any part of the standard. The change submittal form, instructions, and deadlines may be obtained in electronic form from the ASHRAE Web site (www.ashrae.org) or in paper form from the Manager of Standards. The latest edition of an ASHRAE Standard may be purchased from the ASHRAE Web site (www.ashrae.org) or from ASHRAE Customer Service, 1791 Tullie Circle, NE, Atlanta, GA 30329-2305. E-mail: orders@ashrae.org. Fax: 678-539-2129. Telephone: 404-636-8400 (worldwide), or toll free 1-800-527-4723 (for orders in US and Canada). For reprint permission, go to www.ashrae.org/permissions.

 ISSN 1041-2336

ASHRAE®

ASHE®
American Society for Healthcare Engineering
of the American Hospital Association

Approved American National Standard
ANSI
www.ansi.org

SPECIAL NOTE

This American National Standard (ANS) is a national voluntary consensus standard developed under the auspices of ASHRAE. *Consensus* is defined by the American National Standards Institute (ANSI), of which ASHRAE is a member and which has approved this standard as an ANS, as "substantial agreement reached by directly and materially affected interest categories. This signifies the concurrence of more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that an effort be made toward their resolution." Compliance with this standard is voluntary until and unless a legal jurisdiction makes compliance mandatory through legislation.

ASHRAE obtains consensus through participation of its national and international members, associated societies, and public review.

ASHRAE Standards are prepared by a Project Committee appointed specifically for the purpose of writing the Standard. The Project Committee Chair and Vice-Chair must be members of ASHRAE; while other committee members may or may not be ASHRAE members, all must be technically qualified in the subject area of the Standard. Every effort is made to balance the concerned interests on all Project Committees.

The Manager of Standards of ASHRAE should be contacted for:

a. interpretation of the contents of this Standard,
b. participation in the next review of the Standard,
c. offering constructive criticism for improving the Standard, or
d. permission to reprint portions of the Standard.

DISCLAIMER

ASHRAE uses its best efforts to promulgate Standards and Guidelines for the benefit of the public in light of available information and accepted industry practices. However, ASHRAE does not guarantee, certify, or assure the safety or performance of any products, components, or systems tested, installed, or operated in accordance with ASHRAE's Standards or Guidelines or that any tests conducted under its Standards or Guidelines will be nonhazardous or free from risk.

ASHRAE INDUSTRIAL ADVERTISING POLICY ON STANDARDS

ASHRAE Standards and Guidelines are established to assist industry and the public by offering a uniform method of testing for rating purposes, by suggesting safe practices in designing and installing equipment, by providing proper definitions of this equipment, and by providing other information that may serve to guide the industry. The creation of ASHRAE Standards and Guidelines is determined by the need for them, and conformance to them is completely voluntary.

In referring to this Standard or Guideline and in marking of equipment and in advertising, no claim shall be made, either stated or implied, that the product has been approved by ASHRAE.

CONTENTS

ANSI/ASHRAE/ASHE Standard 170-2013, Ventilation of Health Care Facilities

SECTION		PAGE
Foreword		2
1	Purpose	2
2	Scope	2
3	Definitions	2
4	Compliance	3
5	Planning	4
6	Systems and Equipment	4
7	Space Ventilation	7
8	Planning, Construction, and System Startup	14
9	Normative References	15
Informative Appendix A—Operations and Maintenance Procedures		16
Informative Appendix B—Informative References and Bibliography		17
Informative Appendix C—Addenda Description Information		18

NOTE

Approved addenda, errata, or interpretations for this standard can be downloaded free of charge from the ASHRAE Web site at www.ashrae.org/technology.

(This foreword is not part of this standard. It is merely informative and does not contain requirements necessary for conformance to the standard. It has not been processed according to the ANSI requirements for a standard and may contain material that has not been subject to public review or a consensus process. Unresolved objectors on informative material are not offered the right to appeal at ASHRAE or ANSI.)

FOREWORD

ANSI/ASHRAE/ASHE Standard 170, Ventilation of Health Care Facilities, *is one of a family of documents that offers guidance, regulation, and mandates to designers of health care facilities. It is first and foremost a mandatory minimum requirement and, as such, may not always offer the state-of-the-art best practice for health care ventilation design. Other publications, such as the ASHRAE* HVAC Design Manual for Hospitals and Clinics, 2nd Edition, *complement the standard, providing additional depth and detail for the designer. In addition, the health care designer must refer to any design requirements from the appropriate jurisdiction that has authority. Many jurisdictions use or refer to* Guidelines for Design and Construction of Health Care Facilities, *published by the Facility Guidelines Institute (FGI). Where practical, the committee was cognizant of these other documents in the development of this standard.*

Ventilation design for health care spaces is a combination of tasks that leads to a set of documents used in construction. One such task requires medical planners to develop departmental programs of spaces. These programs include space names that suggest the use for which the space is intended, and health care ventilation designers depend upon these names to determine the ventilation parameters for their designs. This standard provides these ventilation parameters.

Ventilation systems and designs for health care facilities are intended to provide a comfortable environment for patients, health care workers, and visitors while diluting, capturing and exhausting airborne contaminants including potentially infectious airborne agents such as M. tuberculosis. *Without high-quality ventilation in health care facilities, patients, health care workers, and visitors can become exposed to contaminants through normal respiration of particles in the air. Poorly ventilated health care facilities may increase the concentration of airborne contaminants including fungi or mold, which may cause allergic responses in even healthy workers and occupants. Some patients are profoundly immunosuppressed for prolonged periods and, if exposed, are highly susceptible to infection from fungi. For such patients, fungal spores become invasive pathogens and lead to high rates of severe morbidity and mortality. For all these reasons, and considering the various occupancies and patient populations, great care must be taken in the design of health care ventilation systems.*

1. PURPOSE

The purpose of this standard is to define ventilation system design requirements that provide environmental control for comfort, asepsis, and odor in health care facilities.

2. SCOPE

2.1 The requirements in this standard apply to patient-care areas and related support areas within health care facilities, including hospitals, nursing facilities, and outpatient facilities.

2.2 This standard applies to new buildings, additions to existing buildings, and those alterations to existing buildings that are identified within this standard.

2.3 This standard considers chemical, physical, and biological contaminants that can affect the delivery of medical care to patients; the convalescence of patients; and the safety of patients, health care workers, and visitors.

3. DEFINITIONS

absorption distance: the distance downstream of a humidifier required for all moisture to be absorbed into the airstream.

addition: an extension or increase in floor area or height of a *building*, building system, or equipment.

airborne infection isolation (AII): the isolation of patients infected with organisms spread by airborne droplet nuclei less than 5 µm in diameter (see FGI [2010] in Informative Appendix B). For the purposes of this standard, the abbreviation "AII" refers to the room that provides isolation.

airborne infection isolation room: a room that is designed according to the requirements of this standard and that is intended to provide airborne infection isolation.

alteration: a significant change in the function or size of a space, in the use of its systems, or in the use of its equipment, either through rearrangement, replacement, or addition. Routine maintenance and service shall not constitute an alteration.

authority having jurisdiction: the agent or agency responsible for enforcing this standard.

average velocity: the volumetric flow rate obtained by dividing the air quantity issuing from an air distribution device by the nominal face area of the device.

building: a structure that is wholly or partially enclosed within exterior walls and a roof, or within exterior and party walls and a roof, and that affords shelter to persons, animals, or property. In this standard, a building is a structure intended for use as a hospital or health care facility.

classification of surgeries:

> ***procedure room (Class A surgery):*** provides minor surgical procedures performed under topical, local, or regional anesthesia without preoperative sedation. Excluded are intravenous, spinal, and epidural procedures, which are Class B or C surgeries.
>
> ***operating room (Class B surgery):*** provides minor or major surgical procedures performed in conjunction with oral, parenteral, or intravenous sedation or performed with the patient under analgesic or dissociative drugs.
>
> ***operating room (Class C surgery):*** provides major surgical procedures that require general or regional block anesthesia and/or support of vital bodily functions.

(For more information on this method of classifying surgeries, see ACS (2000) in Informative Appendix B.)

equipment: devices for heating, ventilating, and/or air conditioning, including but not limited to furnaces, boilers, air conditioners, heat pumps, chillers, and heat exchangers.

essential accessories: those components of a system required to allow proper operation of that system that are reasonably subject to mechanical failure (e.g., pumps, fans, control air compressors). Humidifiers, controls, and tanks are not included in this definition.

high-risk immunocompromised patients: patients who have the greatest risk of infection caused by airborne or waterborne microorganisms. These patients include but are not limited to allogeneic stem-cell transplant patients and intensive chemotherapy patients.

infection control risk assessment (ICRA): a determination of the potential risk of transmission of various infectious agents in the facility, a classification of those risks, and a list of required practices for mitigating those risks during construction or renovation.

immunocompromised patients: patients whose immune mechanisms are deficient because of immunologic disorders (e.g., human immunodeficiency virus [HIV] infection or congenital immune deficiency syndrome), chronic diseases (e.g., diabetes, cancer, emphysema, or cardiac failure), or immunosuppressive therapy (e.g., radiation, cytotoxic chemotherapy, antirejection medication, or steroids) (see CDC [2003] in Informative Appendix B).

inpatient: a patient whose stay at the health care facility is anticipated to require twenty-four hours or more of patient care.

invasive imaging procedure room: a room in which radiographic imaging is used and in which instruments or devices are inserted into patients through the skin or body orifice under sterile conditions for diagnosis and/or treatment.

nonaspirating diffuser: a diffuser that has unidirectional downward airflow from the ceiling with minimum entrainment of room air. Classified as ASHRAE Group E, these diffusers generally have very low average velocity. For the purposes of this standard, the performance of these diffusers is to be measured in terms of average velocity.

nursing facility: a facility that provides resident care, treatment, and services areas (including skilled nursing, subacute care, and Alzheimer's and other dementia facilities).

patient-care area: an area used primarily for the provision of clinical care to patients. Such care includes monitoring, evaluation, and treatment services.

protective environment (PE) room: a patient room that is designed according to this standard and intended to protect a high-risk immunocompromised patient from human and environmental airborne pathogens.

triage: the process of determining the severity of the illness of or injury to patients so that those who have the most emergent illnesses/injuries can be treated immediately and those less severely injured can be treated later or in another area.

4. COMPLIANCE

4.1 Compliance Requirements

4.1.1 New Buildings. New buildings shall comply with the provisions of this standard.

4.1.2 Existing Buildings

4.1.2.1 Additions to Existing Buildings. Additions shall comply with the provisions of this standard.

4.1.2.2 Alterations to Existing Buildings. Portions of a heating, ventilating, and air-conditioning system and other systems and equipment that are being altered shall comply with the applicable requirements of this standard.

4.1.2.2.1 Heating, Ventilation, and Air-Conditioning System Alterations. Alterations to mechanical systems serving the building heating, cooling, or ventilating needs shall comply with the requirements of Section 6, "Systems and Equipment," applicable to those specific portions of the building and its systems that are being altered. Any new mechanical equipment installed in conjunction with the alteration as a direct replacement of existing mechanical equipment shall comply with the provisions of Sections 6.2, 6.4, 6.5, and 6.6.

4.1.2.2.2 Space Alterations. Alterations to spaces listed in Table 6.4 shall comply with the requirements of Section 6.7 and Section 7, "Space Ventilation," applicable to those specific portions of the building and its systems that are being altered. Any alteration to existing health care space in a building that will continue to treat patients during construction shall comply with Sections 8.1, 8.3, 8.4, and 8.5.

4.2 Administrative Requirements. Administrative requirements relating to permit requirements, enforcement by the authority having jurisdiction, interpretations, claims of exemption, approved calculation methods, rights of approved calculation methods, and rights of appeal are specified by the authority having jurisdiction.

4.3 Compliance Documents

4.3.1 General. Compliance documents are those plans, specifications, engineering calculations, diagrams, reports, and other data that are approved as part of the permit by the authority having jurisdiction. The compliance documents shall include all specific construction-related requirements of the owner's infection control risk assessment.

4.3.2 Construction Details. Compliance documents shall contain all pertinent data and features of the building, equipment, and systems in sufficient detail to allow a determination of compliance by the authority having jurisdiction and to indicate compliance with the requirements of this standard.

4.3.3 Supplemental Information. Supplemental information necessary to verify compliance with this standard, such as calculations, worksheets, compliance forms, vendor literature, or other data, shall be made available when required by the authority having jurisdiction.

4.4 Alternate Materials, Methods of Construction, or Design. The provisions of this standard are not intended to prevent the use of any material, method of construction, design, or building system not specifically prescribed herein, provided such construction, design, or building system has

been approved by the authority having jurisdiction as meeting the intent of this standard.

4.5 Informative Appendices. The informative appendices to this standard and informative notes located within this standard contain recommendations, explanations, and other nonmandatory information and are not part of this standard.

4.6 Criteria Ranges. This standard often specifies a range of values that will comply with a specific requirement of the standard. If it is permitted by the authority having jurisdiction, compliance with this requirement may be achieved by the presentation of compliance documents that demonstrate a system's ability to perform within the specified range.

5. PLANNING

Owners/managers of health care facilities shall prepare a detailed program that shall include the clinical service expected in each space, the specific user equipment expected to be used in each space, and any special clinical needs for temperature, humidity, and pressure control. This program shall be prepared in the planning phase of design.

6. SYSTEMS AND EQUIPMENT

Air-handling and distribution systems are required to provide health care facilities not only with a comfortable environment but also with ventilation to dilute and remove contaminants, to provide conditioned air, and to assist in controlling the transmission of airborne infection. In order to meet these requirements, air-handling and distribution systems shall be designed according to the requirements of this standard.

6.1 Utilities

6.1.1 Ventilation Upon Loss of Electrical Power. The space ventilation and pressure relationship requirements of Table 7.1 be maintained for the following spaces, even in the event of loss of normal electrical power:

a. AII rooms
b. PE rooms
c. Operating rooms (Class B and C surgery), including delivery rooms (Caesarean)

(For further information, see NFPA [2012] in Informative Appendix B.)

6.1.2 Heating and Cooling Sources

6.1.2.1 Provide heat sources and essential accessories in number and arrangement sufficient to accommodate the facility needs (reserve capacity), even when any one of the heat sources or essential accessories is not operating due to a breakdown or routine maintenance. The capacity of the remaining source(s) shall be sufficient to provide for domestic hot water, sterilization, and dietary purposes and to provide heating for operating, delivery, birthing, labor, recovery, emergency, intensive care, nursery, and inpatient rooms. (For further information, see FGI [2010] in Informative Appendix B.) Fuel sufficient to support the owner's facility operation plan upon loss of fuel service shall be provided on site.

Exception: Reserve capacity is not required if the ASHRAE 99% heating dry-bulb temperature for the facility is greater than or equal to 25°F (–4°C).

6.1.2.2 For central cooling systems greater than 400 tons (1407 kW) peak cooling load, the number and arrangement of cooling sources and essential accessories shall be sufficient to support the owner's facility operation plan upon a breakdown or routine maintenance of any one of the cooling sources.

6.2 Air-Handling-Unit Design

6.2.1 Air-Handling-Unit Casing. The casing of the air-handling unit shall be designed to prevent water intrusion, resist corrosion, and permit access for inspection and maintenance. All airstream surfaces of air-handling units—e.g., interior surfaces and components—shall comply with Section 5.4 of ANSI/ASHRAE Standard 62.1, *Ventilation for Acceptable Indoor Air Quality.*[12] (For more information, see ASHRAE [2010b, 2005b] in Informative Appendix B.)

6.3 Outdoor Air Intakes and Exhaust Discharges

6.3.1 Outdoor Air Intakes

6.3.1.1 General. Outdoor air intakes for air-handling units shall be located a minimum of 25 ft (8 m) from cooling towers and all exhaust and vent discharges. Outdoor air intakes shall be located such that the bottom of the air intake is at least 6 ft (2 m) above grade. New facilities with moderate-to-high risk of natural or man-made extraordinary incidents shall locate air intakes away from public access. All intakes shall be designed to prevent the entrainment of wind-driven rain, shall contain features for draining away precipitation, and shall be equipped with a birdscreen of mesh no smaller than 0.5 in. (13 mm).

6.3.1.2 Relief Air. Relief air is exempt from the 25-foot (8-metre) separation requirement. Relief air is defined as the Class 1 air (for further information see Standard 62.1 [ASHRAE 2010b] in Informative Appendix B) that could be returned to the air-handling unit from the occupied spaces but is being discharged to the outdoors to maintain building pressurization (such as during air-side economizer operation).

Roof Locations. Intakes on top of buildings shall be located with the bottom of the air intake a minimum of 3 ft (1 m) above roof level.

6.3.1.3 Areaways. In the case of an areaway, the bottom of the air intake opening shall be at least 6 ft (2 m) above grade. The bottom of the air intake opening from the areaway into the building shall be at least 3 ft (1 m) above the bottom of the areaway. (See Figure A-3 in Informative Appendix A.)

6.3.2 Exhaust Discharges. Exhaust discharge outlets that discharge air from AII rooms, bronchoscopy rooms, emergency department waiting rooms, nuclear medicine laboratories, radiology waiting rooms, and laboratory chemical fume hoods shall

a. be designed so that all ductwork within the building is under negative pressure;

Exception: Ductwork located within mechanical equipment rooms. Positive-pressure exhaust ductwork located within mechanical equipment rooms shall be sealed in accordance with SMACNA duct leakage Seal Class A.[10]

TABLE 6.4 Minimum Filter Efficiencies

Space Designation (According to Function)	Filter Bank No. 1 (MERV)[a]	Filter Bank No. 2 (MERV)[a]
Operating rooms (Class B and C surgery); inpatient and ambulatory diagnostic and therapeutic radiology; inpatient delivery and recovery spaces	7	14
Inpatient care, treatment, and diagnosis, and those spaces providing direct service or clean supplies and clean processing (except as noted below); AII (rooms)	7	14
Protective environment (PE) rooms	7	HEPA[c,d]
Laboratories; Procedure rooms (Class A surgery), and associated semirestricted spaces	13[b]	NR
Administrative; bulk storage; soiled holding spaces; food preparation spaces; and laundries	7	NR
All other outpatient spaces	7	NR
Nursing facilities	13	NR
Psychiatric hospitals	7	NR
Resident care, treatment, and support areas in inpatient hospice facilities	13	NR
Resident care, treatment, and support areas in assisted living facilities	7	NR

NR = not required

Notes:

a. The minimum efficiency reporting value (MERV) is based on the method of testing described in ANSI/ASHRAE Standard 52.2, *Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size* ([ASHRAE 2012] in Informative Appendix B).

b. Additional prefilters may be used to reduce maintenance for filters with efficiencies higher than MERV 7.

c. As an alternative, MERV-14 rated filters may be used in Filter Bank No. 2 if a tertiary terminal HEPA filter is provided for these spaces.

d. High-Efficiency Particulate Air (HEPA) filters are those filters that remove at least 99.97% of 0.3 micron-sized particles at the rated flow in accordance with the testing methods of IEST RP-CC001.3 (IEST [2005] in Informative Appendix B).

b. discharge in a vertical direction at least 10 ft (3 m) above roof level and shall be located not less than 10 ft horizontally from air intakes, openable windows/doors, or areas that are normally accessible to the public or maintenance personnel and that are higher in elevation than the exhaust discharge; and

c. be located such that they minimize the recirculation of exhausted air back into the building.

6.4 Filtration. Filter banks shall be provided in accordance with Table 6.4. Each filter bank with an efficiency of greater than MERV 12 shall be provided with an installed manometer or differential pressure measuring device that is readily accessible and provides a reading of differential static pressure across the filter to indicate when the filter needs to be changed. (For further information, see FGI [2010] and CDC [2003] in Informative Appendix B.) All of the air provided to a space shall be filtered in accordance with Table 6.4, except as otherwise indicated in Section 7.1 for spaces that allow recirculating HVAC room units.

6.4.1 First Filtration Bank. Filter Bank No. 1 shall be placed upstream of the heating and cooling coils such that all mixed air is filtered.

6.4.2 Second Filtration Bank. Filter Bank No. 2 shall be installed downstream of all wet-air cooling coils and the supply fan. All second filter banks shall have sealing interface surfaces.

6.4.3 Filter Bank Blank-Off Panels. Filter bank blank-off panels shall be permanently attached to the filter bank frame, constructed of rigid materials, and have sealing surfaces equal to or greater than the filter media installed within the filter bank frame.

6.4.4 Filter Frames. Filter frames shall be durable and proportioned to provide an airtight fit with the enclosing ductwork. All joints between filter segments and enclosing ductwork shall have gaskets or seals to provide a positive seal against air leakage.

6.5 Heating and Cooling Systems

6.5.1 Cooling Coils and Drain Pans. Cooling coils and drain pans shall comply with the requirements of ANSI/ASHRAE Standard 62.1.[12]

6.5.2 Radiant Cooling Systems. If radiant cooling panels are utilized, the chilled-water temperature shall always remain above the dew-point temperature of the space.

6.5.3 Radiant Heating Systems. If radiant heating is provided for an AII room, a protective environment room, a wound intensive-care unit (burn unit), an operating room or a procedure room (for any class of surgery), either flat and smooth radiant ceiling or wall panels with exposed cleanable surfaces or radiant floor heating shall be used. Gravity-type heating or cooling units, such as radiators or convectors, shall not be used in operating rooms and other special-care areas.

6.5.4 Cooling Towers. Cooling towers shall be located so that drift is directed away from air-handling unit intakes. They shall meet the requirements of Section 6.3.2.

6.6 Humidifiers. When outdoor humidity and internal moisture sources are not sufficient to meet the requirements of

TABLE 6.7.2 Supply Air Outlets

Space Designation (According to Function)	Supply Air Outlet Classification[a]
Operating rooms, procedure rooms (all class A, B, and C surgeries[b])	Primary supply diffusers Group E, nonaspirating additional supply diffusers, Group E
Protective environment (PE) rooms	Group E, nonaspirating
Wound intensive-care units (burn units)	Group E, nonaspirating
Trauma rooms (crisis or shock)	Group E, nonaspirating
AII rooms	Group A or Group E
Single-bed patient rooms[c]	Group A, Group D, or Group E
All other patient-care spaces	Group A or Group E
All other spaces	No requirement

Notes:

a. Refer to the 2009 *ASHRAE Handbook—Fundamentals*, Chapter 20 (see ASHRAE [2009] in Informative Appendix B), for definitions related to outlet classification and performance.

b. Surgeons may require alternate air distribution systems for some specialized surgeries. Such systems shall be considered acceptable if they meet or exceed the requirements of this standard.

c. Air distribution systems using Group D diffusers shall meet the following requirements:
   1. The system shall be designed according to "Design Guidelines" in Chapter 7 of *ASHRAE System Performance Evaluation and Design Guidelines for Displacement Ventilation*.[11]
   2. The supply diffuser shall be located where it cannot be permanently blocked (e.g., opposite the foot of the bed.)
   3. The room return/exhaust grille shall be located in the ceiling, approximately above the head of the patient bed.
   4. The transfer grille to the toilet room shall be located above the occupied zone.

Table 7.1, humidification shall be provided by means of the health-care facility air-handling systems. Locate humidifiers within air-handling units or ductwork to avoid moisture accumulation in downstream components, including filters and insulation. Steam humidifiers shall be used. Chemical additives used for steam humidifiers serving health care facilities shall comply with FDA requirements.[1] A humidity sensor shall be provided, located at a suitable distance downstream from the steam injection source. Controls shall be provided to limit duct humidity to a maximum value of 90% rh when the humidifier is operating. Humidifier steam control valves shall be designed so that they remain off whenever the air-handling unit is not in operation. Duct takeoffs shall not be located within the humidifier's absorption distance.

6.7 Air Distribution Systems

6.7.1 General. Maintain the pressure relationships required in Table 7.1 in all modes of HVAC system operation, except as noted in the table. Spaces listed in Table 7.1 that have required pressure relationships shall be served by fully ducted return systems or fully ducted exhaust systems. The following additional surgery and critical-care patient-care areas that do not require a pressure relationship to adjacent areas shall also be served by fully ducted return or exhaust systems: (1) recovery rooms, (2) critical- and intensive-care areas, (3) intermediate-care areas, and (4) wound intensive-care units (burn units). In inpatient facilities, patient-care areas shall utilize ducted systems for return and exhaust air. Where space pressure relationships are required, the air distribution system design shall maintain them, taking into account recommended maximum filter loading, heating-season lower airflow operation, and cooling-season higher airflow operation. Airstream surfaces of the air distribution system downstream of Filter Bank No. 2, shall comply with Section 5.4 of ANSI/ASHRAE Standard 62.1.[12] The air distribution system shall be provided with access doors, panels, or other means to allow convenient access for inspection and cleaning. (For further information, see ASHRAE Standard 62.1 [2010b] in Informative Appendix B.)

6.7.2 Air Distribution Devices. All air distribution devices shall meet the following requirements:

a. Surfaces of air distribution devices shall be suitable for cleaning. Supply air outlets in accordance with Table 6.7.2 shall be used.
b. The supply diffusers in operating rooms (Classes B and C surgeries) shall be designed and installed to allow for internal cleaning.
c. Psychiatric, seclusion, and holding-patient rooms shall be designed with security diffusers, grilles, and registers.

6.7.3 Smoke Barriers. Where smoke barriers are required, heating, ventilating, and air-conditioning zones shall be coordinated with compartmentation to minimize ductwork penetrations of fire and smoke barriers

6.7.4 Smoke and Fire Dampers

a. Maintenance access shall be provided at all dampers.
b. All damper locations shall be shown on design drawings.
c. Air-handling systems shall be arranged such that damper activation will not damage ducts.

6.7.5 Duct Penetrations. Ducts that penetrate construction intended to protect against x-ray, magnetic, radio frequency interference (RFI), or other radiation shall not impair the effectiveness of the protection, nor shall the treatment of these penetrations impair the ventilation of the space served.

6.8 Energy Recovery Systems

6.8.1 General. Energy recovery systems shall be located upstream of Filter Bank No. 2. If energy recovery systems are utilized, the systems shall not allow for any amount of cross-contamination of exhaust air back to the supply airstream via

purge, leakage, carryover, or transfer except as allowed in Section 6.8.3.

6.8.2 Airborne Infectious Isolation Room Exhaust Systems. Airborne infectious isolation room exhaust systems serving AII rooms or combination AII/PE rooms shall not be utilized for energy recovery.

Exception: Airborne infectious isolation room exhaust systems serving AII rooms or combination AII/PE rooms may be served by an energy recovery system where the supply airstream components and the exhaust airstream components are fully separated by an air gap of adequate distance to prevent cross-contamination that is open to the atmosphere (e.g., run-around pumped coils).

6.8.3 Energy Recovery Systems with Leakage Potential. If energy recovery systems with leakage potential are utilized, they shall be arranged to minimize the potential to transfer exhaust air directly back into the supply airstream. Energy recovery systems with leakage potential shall be designed to have no more than 5% of the total supply airstream consisting of exhaust air. Energy recovery systems with leakage potential shall not be utilized from these exhaust airstream sources: ER waiting rooms, triage, ER decontamination, radiology waiting rooms, darkroom, bronchoscopy sputum collection and pentamidine administration, laboratory fume hood and other directly ducted laboratory equipment exhaust, waste anesthesia gas disposal, autopsy, nonrefrigerated body holding, endoscope cleaning, central medical and surgical supply soiled or decontamination room, laundry general, hazardous material storage, dialyzer reprocessing room, nuclear medicine hot lab, nuclear medicine treatment room, and any other space identified by the authority having jurisdiction or the ICRA team.

6.9 Insulation and Duct Lining

a. An exterior vapor barrier shall be provided for insulation on cold surfaces. A vapor barrier is not required for insulation materials that do not absorb or transmit moisture.
b. Existing insulation and duct lining accessible during a renovation project shall be inspected, repaired, and/or replaced as appropriate.
c. Duct lining shall not be used in ductwork located downstream of Filter Bank No. 2. Duct lining with an impervious cover may be allowed in terminal units, sound attenuators, and air distribution devices downstream of Filter Bank No. 2. This lining and cover shall be factory installed.
d. Duct lining shall not be installed within 15 ft (4.57 m) downstream of humidifiers.

7. SPACE VENTILATION

The ventilation requirements of this standard are minimums that provide control of environmental comfort, asepsis, and odor in health care facilities. However, because they are minimum requirements and because of the diversity of the population and variations in susceptibility and sensitivity, these requirements do not provide assured protection from discomfort, airborne transmission of contagions, and odors.

7.1 General Requirements. The following general requirements shall apply for space ventilation:

a. Spaces shall be ventilated according to Table 7.1.
   1. Design of the ventilation system shall provide air movement that is generally from clean to less clean areas. If any form of variable-air-volume or load-shedding system is used for energy conservation, it shall not compromise the pressure balancing relationships or the minimum air changes required by the table.
   2. The ventilation rates in this table are intended to provide for comfort as well as for asepsis and odor control in areas of a health care facility that directly affect patient care. Ventilation rates for many areas not specified here can be found in ANSI/ASHRAE Standard 62.1 (ASHRAE [2010b] in Informative Appendix B). Where areas with prescribed rates in both Standard 62.1[12] and Table 7.1 of this standard exist, the higher of the two air change rates shall be used.
   3. For design purposes, the minimum number of total air changes indicated shall be either supplied for positive pressure rooms or exhausted for negative pressure rooms. Spaces that are required in Table 7.1 to be at a negative pressure relationship and are not required to be exhausted shall utilize the supply airflow rate to compute the minimum total air changes per hour required. For spaces that require a positive or negative pressure relationship, the number of air changes can be reduced when the space is unoccupied, provided that the required pressure relationship to adjoining spaces is maintained while the space is unoccupied and that the minimum number of air changes indicated is re-established anytime the space becomes occupied. Air change rates in excess of the minimum values are expected in some cases in order to maintain room temperature and humidity conditions based upon the space cooling or heating load.
   4. The entire minimum outdoor air changes per hour required by Table 7.1 for the space shall meet the filtration requirements of Section 6.4.
   5. For spaces where Table 7.1 permits air to be recirculated by room units, the portion of the minimum total air changes per hour required for a space that is greater than the minimum outdoor air changes per hour required component may be provided by recirculating room HVAC units. Such recirculating room HVAC units shall
      i. not receive nonfiltered, nonconditioned outdoor air;
      ii. serve only a single space; and
      iii. provide a minimum MERV 6 filter for airflow passing over any surface that is designed to condense water. This filter shall be located upstream of any such cold surface, so that all of the air passing over the cold surface is filtered.
   6. For air-handling systems serving multiple spaces, system minimum outdoor air quantity shall be calculated utilizing one of the following methods:
      i. System minimum outdoor air quantity for an air-handling system shall be calculated as the sum of the individual space requirements as defined by this standard.

TABLE 7.1 Design Parameters

Function of Space	Pressure Relationship to Adjacent Areas (n)	Minimum Outdoor ach	Minimum Total ach	All Room Air Exhausted Directly to Outdoors (j)	Air Recirculated by Means of Room Units (a)	Design Relative Humidity (k), %	Design Temperature (l), °F/°C
SURGERY AND CRITICAL CARE							
Operating room (Class B and C) (m), (n), (o)	Positive	4	20	NR	No	20–60	68–75/20–24
Operating/surgical cystoscopic rooms, (m), (n) (o)	Positive	4	20	NR	No	20–60	68–75/20–24
Delivery room (Caesarean) (m), (n), (o)	Positive	4	20	NR	No	20–60	68–75/20–24
Substerile service area	NR	2	6	NR	No	NR	NR
Recovery room	NR	2	6	NR	No	20–60	70–75/21–24
Critical and intensive care	NR	2	6	NR	No	30–60	70–75/21–24
Intermediate care (s)	NR	2	6	NR	NR	max 60	70–75/21–24
Wound intensive care (burn unit)	NR	2	6	NR	No	40–60	70–75/21–24
Newborn intensive care	Positive	2	6	NR	No	30–60	72–78/22–26
Treatment room (p)	NR	2	6	NR	NR	20–60	70–75/21–24
Trauma room (crisis or shock) (c)	Positive	3	15	NR	No	20–60	70–75/21–24
Medical/anesthesia gas storage (r)	Negative	NR	8	Yes	NR	NR	NR
Laser eye room	Positive	3	15	NR	No	20–60	70–75/21–24
ER waiting rooms	Negative	2	12	Yes (q)	NR	max 65	70–75/21–24
Triage	Negative	2	12	Yes (q)	NR	max 60	70–75/21–24
ER decontamination	Negative	2	12	Yes	No	NR	NR
Radiology waiting rooms	Negative	2	12	Yes (q), (w)	NR	max 60	70–75/21–24
Procedure room (Class A surgery) (o), (d)	Positive	3	15	NR	No	20–60	70–75/21–24
Emergency department exam/treatment room (p)	NR	2	6	NR	NR	max 60	70–75/21–24
INPATIENT NURSING							
Patient room	NR	2	4 (y)	NR	NR	max 60	70–75/21–24
Nourishment area or room	NR	NR	2	NR	NR	NR	NR
Toilet room	Negative	NR	10	Yes	No	NR	NR

Note: NR = no requirement

TABLE 7.1 Design Parameters *(Continued)*

Function of Space	Pressure Relationship to Adjacent Areas (n)	Minimum Outdoor ach	Minimum Total ach	All Room Air Exhausted Directly to Outdoors (j)	Air Recirculated by Means of Room Units (a)	Design Relative Humidity (k), %	Design Temperature (l), °F/°C
Newborn nursery suite	NR	2	6	NR	No	30–60	72–78/22–26
Protective environment room (t)	Positive	2	12	NR	No	max 60	70–75/21–24
AII room (u)	Negative	2	12	Yes	No	max 60	70–75/21–24
Combination AII/PE room	Positive	2	12	Yes	No	Max 60	70-75/21-24
AII anteroom (u)	(e)	NR	10	Yes	No	NR	NR
PE anteroom (t)	(e)	NR	10	NR	No	NR	NR
Combination AII/PE anteroom	(e)	NR	10	Yes	No	NR	NR
Labor/delivery/recovery/postpartum (LDRP) (s)	NR	2	6	NR	NR	max 60	70–75/21–24
Labor/delivery/recovery (LDR) (s)	NR	2	6	NR	NR	max 60	70–75/21–24
Patient Corridor	NR	NR	2	NR	NR	NR	NR
NURSING FACILITY							
Resident room	NR	2	2	NR	NR	NR	70–75/21–24
Resident gathering/activity/dining	NR	4	4	NR	NR	NR	70–75/21–24
Resident unit corridor	NR	NR	4	NR	NR	NR	NR
Physical therapy	Negative	2	6	NR	NR	NR	70–75/21–24
Occupational therapy	NR	2	6	NR	NR	NR	70–75/21–24
Bathing room	Negative	NR	10	Yes	No	NR	70–75/21–24
RADIOLOGY (v)							
X-ray (diagnostic and treatment)	NR	2	6	NR	NR	max 60	72–78/22–26
X-ray (surgery/critical care and catheterization)	Positive	3	15	NR	No	max 60	70–75/21–24
Darkroom (g)	Negative	2	10	Yes	No	NR	NR
DIAGNOSTIC AND TREATMENT							
Bronchoscopy, sputum collection, and pentamidine administration (n)	Negative	2	12	Yes	No	NR	68–73/20–23

Note: NR = no requirement

TABLE 7.1 Design Parameters *(Continued)*

Function of Space	Pressure Relationship to Adjacent Areas (n)	Minimum Outdoor ach	Minimum Total ach	All Room Air Exhausted Directly to Outdoors (j)	Air Recirculated by Means of Room Units (a)	Design Relative Humidity (k), %	Design Temperature (l), °F/°C
Laboratory, general (v)	Negative	2	6	NR	NR	NR	70–75/21–24
Laboratory, bacteriology (v)	Negative	2	6	Yes	NR	NR	70–75/21–24
Laboratory, biochemistry (v)	Negative	2	6	Yes	NR	NR	70–75/21–24
Laboratory, cytology (v)	Negative	2	6	Yes	NR	NR	70–75/21–24
Laboratory, glasswashing	Negative	2	10	Yes	NR	NR	NR
Laboratory, histology (v)	Negative	2	6	Yes	NR	NR	70–75/21–24
Laboratory, microbiology (v)	Negative	2	6	Yes	NR	NR	70–75/21–24
Laboratory, nuclear medicine (v)	Negative	2	6	Yes	NR	NR	70–75/21–24
Laboratory, pathology (v)	Negative	2	6	Yes	NR	NR	70–75/21–24
Laboratory, serology (v)	Negative	2	6	Yes	NR	NR	70–75/21–24
Laboratory, sterilizing	Negative	2	10	Yes	NR	NR	70–75/21–24
Laboratory, media transfer (v)	Positive	2	4	NR	NR	NR	70–75/21–24
Nonrefrigerated body-holding room (h)	Negative	NR	10	Yes	No	NR	70–75/21–24
Autopsy room (n)	Negative	2	12	Yes	No	NR	68–75/20–24
Pharmacy (b)	Positive	2	4	NR	NR	NR	NR
Examination room	NR	2	6	NR	NR	max 60	70–75/21–24
Medication room	NR	2	4	NR	NR	max 60	70–75/21–24
Gastrointestinal endoscopy procedure room (x)	NR	2	6	NR	No	20–60	68–73/20–23
Endoscope cleaning	Negative	2	10	Yes	No	NR	NR
Treatment room (x)	NR	2	6	NR	NR	max 60	70–75/21–24
Hydrotherapy	Negative	2	6	NR	NR	NR	72–80/22–27
Physical therapy	Negative	2	6	NR	NR	Max 65	72–80/22–27
Dialysis treatment area	NR	2	6	NR	NR	NR	72–78/22–26
Dialyzer reprocessing room	Negative	NR	10	Yes	No	NR	NR

Note: NR = no requirement

TABLE 7.1 Design Parameters *(Continued)*

Function of Space	Pressure Relationship to Adjacent Areas (n)	Minimum Outdoor ach	Minimum Total ach	All Room Air Exhausted Directly to Outdoors (j)	Air Recirculated by Means of Room Units (a)	Design Relative Humidity (k), %	Design Temperature (l), °F/°C
Nuclear medicine hot lab	Negative	NR	6	Yes	No	NR	70–75/21–24
Nuclear medicine treatment room	Negative	2	6	Yes	NR	NR	70–75/21–24
STERILIZING							
Sterilizer equipment room	Negative	NR	10	Yes	No	NR	NR
CENTRAL MEDICAL AND SURGICAL SUPPLY							
Soiled or decontamination room	Negative	2	6	Yes	No	NR	72–78/22–26
Clean workroom	Positive	2	4	NR	No	max 60	72–78/22–26
Sterile storage	Positive	2	4	NR	NR	max 60	72–78/22–26
SERVICE							
Food preparation center (i)	NR	2	10	NR	No	NR	72–78/22–26
Warewashing	Negative	NR	10	Yes	No	NR	NR
Dietary storage	NR	NR	2	NR	No	NR	72–78/22–26
Laundry, general	Negative	2	10	Yes	No	NR	NR
Soiled linen sorting and storage	Negative	NR	10	Yes	No	NR	NR
Clean linen storage	Positive	NR	2	NR	NR	NR	72–78/22–26
Linen and trash chute room	Negative	NR	10	Yes	No	NR	NR
Bedpan room	Negative	NR	10	Yes	No	NR	NR
Bathroom	Negative	NR	10	Yes	No	NR	72–78/22–26
Janitor's closet	Negative	NR	10	Yes	No	NR	NR
SUPPORT SPACE							
Soiled workroom or soiled holding	Negative	2	10	Yes	No	NR	NR
Clean workroom or clean holding	Positive	2	4	NR	NR	NR	NR
Hazardous material storage	Negative	2	10	Yes	No	NR	NR

Note: NR = no requirement

Notes for Table 7.1:

a. Except where indicated by a "No" in this column, recirculating room HVAC units (with heating or cooling coils) are acceptable for providing that portion of the minimum total air changes per hour that is permitted by Section 7.1 (subparagraph [a][5]). Because of the cleaning difficulty and potential for buildup of contamination, recirculating room units shall not be used in areas marked "No." Recirculating devices with HEPA filters shall be permitted in existing facilities as interim, supplemental environmental controls to meet requirements for the control of airborne infectious agents. The design of either portable or fixed systems should prevent stagnation and short circuiting of airflow. The design of such systems shall also allow for easy access for scheduled preventative maintenance and cleaning.
b. Pharmacy compounding areas may have additional air change, differential pressure, and filtering requirements beyond the minimum of this table depending on the type of pharmacy, the regulatory requirements which may include adoption of USP 797), the associated level of risk of the work (see USP [2013] in Informative Appendix B), and the equipment utilized in the spaces.
c. The term *trauma room* as used herein is a first-aid room and/or emergency room used for general initial treatment of accident victims. The operating room within the trauma center that is routinely used for emergency surgery is considered to be an operating room by this standard.
d. Pressure relationships need not be maintained when the room is unoccupied.
e. See Section 7.2 and its subsections for pressure-relationship requirements.
f. This letter is not used in this table.
g. All air need not be exhausted if darkroom equipment has a scavenging exhaust duct attached and meets ventilation standards regarding NIOSH, OSHA, and local employee exposure limits.[2, 3]
h. A nonrefrigerated body-holding room is applicable only to facilities that do not perform autopsies on-site and use the space for short periods while waiting for the body to be transferred.
i. Minimum total air changes per hour (ach) shall be that required to provide proper makeup air to kitchen exhaust systems as specified in ANSI/ASHRAE Standard 154.[4] In some cases, excess exfiltration or infiltration to or from exit corridors compromises the exit corridor restrictions of NFPA 90A,[5] the pressure requirements of NFPA 96,[6] or the maximum defined in the table. During operation, a reduction to the number of air changes to any extent required for odor control shall be permitted when the space is not in use. (See FGI [2010] in Informative Appendix B.)
j. In some areas with potential contamination and/or odor problems, exhaust air shall be discharged directly to the outdoors and not recirculated to other areas. Individual circumstances may require special consideration for air exhausted to the outdoors. To satisfy exhaust needs, constant replacement air from the outdoors is necessary when the system is in operation.
k. The RH ranges listed are the minimum and/or maximum allowable at any point within the design temperature range required for that space.
l. Systems shall be capable of maintaining the rooms within the range during normal operation. Lower or higher temperature shall be permitted when patients' comfort and/or medical conditions require those conditions.
m. National Institute for Occupational Safety and Health (NIOSH) criteria documents regarding occupational exposure to waste anesthetic gases and vapors, and control of occupational exposure to nitrous oxide[7] indicate a need for both local exhaust (scavenging) systems and general ventilation of the areas in which the respective gases are utilized. Refer to NFPA 99 for other requirements.[8]
n. If pressure-monitoring device alarms are installed, allowances shall be made to prevent nuisance alarms. Short-term excursions from required pressure relationships shall be allowed while doors are moving or temporarily open. Simple visual methods such as smoke trail, ball-in-tube, or flutterstrip shall be permitted for verification of airflow direction.
o. Surgeons or surgical procedures may require room temperatures, ventilation rates, humidity ranges, and/or air distribution methods that exceed the minimum indicated ranges.
p. Treatment rooms used for bronchoscopy shall be treated as bronchoscopy rooms. Treatment rooms used for procedures with nitrous oxide shall contain provisions for exhausting anesthetic waste gases.
q. In a recirculating ventilation system, HEPA filters shall be permitted instead of exhausting the air from these spaces to the outdoors provided that the return air passes through the HEPA filters before it is introduced into any other spaces. The entire minimum total air changes per hour of recirculating airflow shall pass through HEPA filters. When these areas are open to larger, nonwaiting spaces, the exhaust air volume shall be calculated based on the seating area of the waiting area. (***Note:*** The intent here is to not require the volume calculation to include a very large space [e.g., an atrium] just because a waiting area opens onto it.)
r. See NFPA 99 for further requirements.[8]
s. For intermediate care, labor/delivery/recovery rooms, and labor/delivery/recovery/postpartum rooms, four total ach shall be permitted when supplemental heating and/or cooling systems (radiant heating and cooling, baseboard heating, etc.) are used.
t. The protective environment airflow design specifications protect the patient from common environmental airborne infectious microbes (i.e., *Aspergillus* spores). Recirculation HEPA filters shall be permitted to increase the equivalent room air exchanges; however, the outdoor air changes are still required. Constant-volume airflow is required for consistent ventilation for the protected environment. The pressure relationship to adjacent areas shall remain unchanged if the PE room is utilized as a normal patient room. Rooms with reversible airflow provisions for the purpose of switching between protective environment and AII functions shall not be permitted.
u. The AII room described in this standard shall be used for isolating the airborne spread of infectious diseases, such as measles, varicella, or tuberculosis. Supplemental recirculating devices using HEPA filters shall be permitted in the AII room to increase the equivalent room air exchanges; however, the minimum outdoor air changes of Table 7.1 are still required. AII rooms that are retrofitted from standard patient rooms from which it is impractical to exhaust directly outdoors may be recirculated with air from the AII room, provided that air first passes through a HEPA filter. When the AII room is not utilized for airborne infection isolation, the pressure relationship to adjacent areas, when measured with the door closed, shall remain unchanged and the minimum total air change rate shall be 6 ach. Switching controls for reversible airflow provisions shall not be permitted.
v. When required, appropriate hoods and exhaust devices for the removal of noxious gases or chemical vapors shall be provided in accordance with NFPA 99.[8]
w. The requirement that all room air is exhausted directly to outdoors applies only to radiology waiting rooms programmed to hold patients who are waiting for chest x-rays for diagnosis of respiratory disease.
x. If the planned space is designated in the organization's operational plan to be utilized for both bronchoscopy and gastrointestinal endoscopy, the design parameters for "bronchoscopy, sputum collection, and pentamidine administration" shall be used.
y. For single-bed patient rooms using Group D diffusers, a minimum of six total ach shall be provided and calculated based on the volume from finished floor to 6 ft (1.83 m) above the floor.

ii. System minimum outdoor air quantity shall be calculated by the Ventilation Rate Procedure (multiple zone formula) of ASHRAE Standard 62.1.[12] The minimum outdoor air change rate listed in this standard shall be interpreted as the V_{oz} (zone outdoor airflow) for purposes of this calculation.

b. Air filtration for spaces shall comply with Table 6.4.

c. Supply air outlets for spaces shall comply with Table 6.7.2.

d. In AII rooms, protective environment rooms, wound intensive-care units (burn units), and operating and procedure rooms (for all classes of surgery), heating with supply air or radiant panels that meet the requirements of Section 6.5.3 shall be provided.

7.2 Additional Room-Specific Requirements

7.2.1 Airborne Infection Isolation (AII) Rooms. Ventilation for AII rooms shall meet the following requirements whenever an infectious patient occupies the room:

a. Each AII room shall comply with requirements of Tables 6.4, 6.7.2, and 7.1. AII rooms shall have a permanently installed device and/or mechanism to constantly monitor the differential air pressure between the room (when occupied by patients with a suspected airborne infectious disease) and the corridor, whether or not there is an anteroom. A local visual means shall be provided to indicate whenever negative differential pressure is not maintained.

b. All air from the AII room shall be exhausted directly to the outdoors.

Exception: AII rooms that are retrofitted from standard patient rooms from which it is impractical to exhaust directly outdoors may be provided with recirculated air from the room's exhaust on the condition that the air first passes through a HEPA filter.

c. All exhaust air from the AII rooms, associated anterooms, and associated toilet rooms shall be discharged directly to the outdoors without mixing with exhaust air from any other non-AII room or exhaust system.

d. Exhaust air grilles or registers in the patient room shall be located directly above the patient bed on the ceiling or on the wall near the head of the bed unless it can be demonstrated that such a location is not practical.

e. The room envelope shall be sealed to limit leakage airflow at 0.01 in. wc (2.5 Pa) differential pressure across the envelope.

f. Differential pressure between AII rooms and adjacent spaces that are not AII rooms shall be a minimum of –0.01 in. wc (–2.5 Pa). Spaces such as the toilet room and the anteroom (if present) that are directly associated with the AII room and open directly into the AII room are not required to be designed with a minimum pressure difference from the AII room but are still required to maintain the pressure relationships to adjacent areas specified in Table 7.1.

g. When an anteroom is provided, the pressure relationships shall be as follows: (1) the AII room shall be at a negative pressure with respect to the anteroom, and (2) the anteroom shall be at a negative pressure with respect to the corridor.

7.2.2 Protective Environment (PE) Rooms. Ventilation for PE rooms shall meet the following requirements:

a. The room envelope shall be sealed to limit leakage airflow at 0.01 in. wc (2.5 Pa) differential pressure across the envelope.

b. Each PE room shall comply with the requirements of Tables 6.4, 6.7.2, and 7.1. PE rooms shall have a permanently installed device and/or mechanism to constantly monitor the differential air pressure between the room and the corridor when occupied by patients requiring a protective environment regardless of whether there is an anteroom. A local visual means shall be provided to indicate whenever positive differential pressure is not maintained.

c. Air distribution patterns within the protective environment room shall conform to the following:

1. Supply air diffusers shall be above the patient bed unless it can be demonstrated that such a location is not practical. Diffuser design shall limit air velocity at the patient bed to reduce patient discomfort. (See ASHRAE Standard 55 [2010a] in Informative Appendix B.)

2. Return/exhaust grilles or registers shall be located near the patient room door.

d. Differential pressure between PE rooms and adjacent spaces that are not PE rooms shall be a minimum of +0.01 in. wc (+2.5 Pa). Spaces such as the toilet room and the anteroom (if present) that are directly associated with the PE room and open directly into the PE room are not required to be designed with a minimum pressure difference from the PE room but are still required to maintain the pressure relationships to adjacent areas specified in Table 7.1.

e. PE rooms retrofitted from standard patient rooms may be ventilated with recirculated air, provided that air first passes through a HEPA filter and the room complies with parts “a” through “d” of Section 7.2.2.

f. When an anteroom is provided, the pressure relationships shall be as follows: (1) the PE room shall be at a positive pressure with respect to the anteroom and (2) the anteroom shall be at a positive pressure with respect to the corridor.

7.2.3 Combination Airborne Infectious Isolation/Protective Environment (AII/PE) Rooms. Ventilation for AII/PE rooms shall meet the following requirements:

a. Supply air diffusers shall be located above the patient bed.

b. Exhaust grilles or registers shall be located near the patient room door.

c. The pressure relationship to adjacent areas for the required anteroom shall be one of the following:

1. The anteroom shall be at a positive pressure with respect to both the AII/PE room and the corridor or common space.

2. The anteroom shall be at a negative pressure with respect to both the AII/PE room and the corridor or common space.

d. AII/PE rooms shall have two permanently installed devices and/or mechanisms to constantly monitor the differential air pressure. One device and/or mechanism shall monitor the pressure differential between the AII/PE room and the anteroom. The second device and/or mechanism shall monitor the pressure differential between the anteroom and the corridor or common space. For each device and/or mechanism, a local visual means shall be provided to indicate whenever differential pressure is not maintained.

7.3 Critical-Care Units

7.3.1 Wound Intensive-Care Units (Burn Units). Burn-unit patient rooms that require humidifiers to comply with Table 7.1 shall be provided with individual humidity control.

7.4 Surgery Rooms

7.4.1 Operating Rooms (Class B and C), Operating/Surgical Cystoscopic Rooms, and Caesarean Delivery Rooms. These rooms shall be maintained at a positive pressure with respect to all adjoining spaces at all times. A pressure differential shall be maintained at a value of at least +0.01 in. wc (2.5 Pa). Each room shall have individual temperature control. These rooms shall be provided with primary supply diffusers that are designed as follows:

a. The airflow shall be unidirectional, downwards, and the average velocity of the diffusers shall be 25 to 35 cfm/ft^2 (127 to 178 L/s/m^2). The diffusers shall be concentrated to provide an airflow pattern over the patient and surgical team. (For further information, see Memarzadeh and Manning [2002] and Memarzadeh and Jiang [2004] in Informative Appendix B.)
b. The area of the primary supply diffuser array shall extend a minimum of 12 in. (305 mm) beyond the footprint of the surgical table on each side. No more than 30% of the primary supply diffuser array area shall be used for nondiffuser uses such as lights, gas columns, etc. Additional supply diffusers may be required to provide additional ventilation to the operating room to achieve the environmental requirements of Table 7.1 relating to temperature, humidity, etc.

The room shall be provided with at least two low sidewall return or exhaust grilles spaced at opposite corners or as far apart as possible, with the bottom of these grilles installed approximately 8 in. (203 mm) above the floor.

Exception: In addition to the required low return (or exhaust) air grilles, such grilles may be placed high on the walls.

7.4.2 Sterilization Rooms. Steam that escapes from a steam sterilizer shall be exhausted using an exhaust hood or other suitable means. Ethylene oxide that escapes from a gas sterilizer shall be exhausted using an exhaust hood or other suitable means.

7.4.3 Imaging Procedure Rooms. If invasive procedures occur in this type of room, ventilation shall be provided in accordance with the ventilation requirements for procedure rooms (Class A surgery). If anesthetic gases are administered, ventilation shall be provided in accordance with the ventilation requirements for operating rooms (Class B or C surgery).

7.5 Support Spaces

7.5.1 Morgue and Autopsy Rooms. Ventilation for morgue and autopsy rooms shall meet the following requirements:

a. Low sidewall exhaust grilles shall be provided unless exhaust air is removed through an autopsy table designed for this purpose.
b. All exhaust air from autopsy, nonrefrigerated body-holding, and morgue rooms shall be discharged directly to the outdoors without mixing with air from any other room or exhaust system.
c. Differential pressure between morgue and autopsy rooms and any adjacent spaces that have other functions shall be a minimum of –0.01 in. wc (–2.5 Pa).

7.5.2 Bronchoscopy

a. Differential pressure between bronchoscopy procedure and sputum induction rooms and any adjacent spaces that have other functions shall be a minimum of –0.01 in. wc (–2.5Pa).
b. Local exhaust shall be provided for sputum collection procedures.

7.6 Psychiatric Patient Areas. All exposed equipment located with these spaces shall have enclosures with rounded corners and tamper-resistant fasteners. With the exception of HVAC room recirculating units, equipment shall be arranged such that maintenance personnel are not required to enter patient-care spaces for service.

8. PLANNING, CONSTRUCTION, AND SYSTEM STARTUP

8.1 Overview. For HVAC systems serving surgery and critical-care spaces, compliance with this standard requires preparation of an acceptance testing plan.

8.2 Planning for the HVAC Services in a New Facility. Design documents for new construction shall meet the following requirements:

a. *General Mechanical Equipment Rooms.* The access to mechanical rooms shall be planned to avoid the intrusion of maintenance personnel into surgical and critical-care patient spaces.
b. *Mechanical Room Layout.* Mechanical room layout shall include sufficient space for access to equipment for operation, maintenance, and replacement. Floors in mechanical rooms shall be sealed, including sealing around all penetrations, when they are above surgical suites and critical care.
c. *Maintenance/Repair Personnel Access.* Safe and practical means of accessing equipment shall be provided. Clearance is required at all service points to mechanical equipment to allow personnel access and working space.

8.3 Planning for the HVAC Services in an Existing Facility. If any existing air-handling equipment is reused, the designer

shall evaluate the capacity of the equipment to determine whether it will meet the requirements of this standard for the remodeled space.

8.4 Planning for Infection Control During Remodeling of an Existing Facility. Prior to beginning modifications or remodeling of HVAC systems in an existing facility, an owner shall conduct an infection control risk assessment (ICRA). The ICRA shall establish those procedures required to minimize the disruption of facility operation and the distribution of dust, odors, and particulates.

8.5 Documentation of New or Remodeled HVAC Systems. Owners shall retain an acceptance testing report for their files. In addition, the design shall include requirements for operations and maintenance staff training that is sufficient for the staff to keep all HVAC equipment in a condition that will maintain the original design intent for ventilation. Training of operating staff shall include an explanation of the design intent. The training materials shall include, at a minimum, the following:

a. O&M procedures
b. Temperature and pressure control operation in all modes
c. Acceptable tolerances for system temperatures and pressures
d. Procedures for operations under emergency power or other abnormal conditions that have been considered in the facility design.

8.6 Duct Cleanliness. The duct supply system shall meet the following requirements for cleanliness:

a. The duct system shall be free of construction debris. New supply duct system installations shall comply with level "B," the Intermediate Level of SMACNA Duct Cleanliness for New Construction Guidelines.[9]
b. The supply diffusers in operating rooms (Class B and C surgery) shall be opened and cleaned before the space is used.
c. The permanent HVAC systems shall not be operated unless protection from contamination of the air distribution system is provided.

9. NORMATIVE REFERENCES

[1] Code of Federal Regulations, 21CFR 173.310 (April 1999), U.S. Dept. of Health and Human Services, Food and Drug Administration.

[2]DHHS (NIOSH) Publication No. 94-100 (NIOSH Alert), *Controlling Exposures to Nitrous Oxide During Anesthetic Administration*, National Institute for Occupational Safety and Health (CDC), Atlanta, GA.

[3]OSHA [1994]. Computerized information system. Washington, DC: U.S. Department of Labor, Occupational Safety and Health Administration.

[4]ANSI/ASHRAE Standard 154-2003, *Ventilation for Commercial Cooking Operations*, Atlanta: ASHRAE.

[5]NFPA. 2002. NFPA 90A, *Standard for the Installation of Air-Conditioning and Ventilating Systems*. National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169.

[6]NFPA. 2004. NFPA 96, *Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations*. National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169.

[7]NIOSH Critical Documents. National Institute for Occupational Safety and Health, available at the Centers for Disease Control and Prevention (CDC) website: http://www.cdc.gov/niosh/pubs/criteria_date_desc_nopubnumbers.html

[8]NFPA 99-2005, *Standard for Health Care Facilities.* National Fire Protection Association, 1 Batterymarch Park, Quincy, Massachusetts USA 02169

[9]SMACNA *Duct Cleanliness for New Construction Guidelines*, (2000), Chantilly, VA 20151.

[10]SMACNA, *HVAC Duct Construction Standards, Metal and Flexible (Third Edition: 2005)*. Chantilly, VA 20151.

[11]*ASHRAE System Performance Evaluation and Design Guidelines for Displacement Ventilation*, 2003. Quigyean Chen and Leon Glickman.

[12]ANSI/ASHRAE Standard 62.1-2010, *Ventilation for Acceptable Indoor Air Quality*, Atlanta: ASHRAE.

(This appendix is not part of this standard. It is merely informative and does not contain requirements necessary for conformance to the standard. It has not been processed according to the ANSI requirements for a standard and may contain material that has not been subject to public review or a consensus process. Unresolved objectors on informative material are not offered the right to appeal at ASHRAE or ANSI.)

INFORMATIVE APPENDIX A
OPERATIONS AND MAINTENANCE PROCEDURES

A1. O&M IN HEALTH CARE FACILITIES

The following operations and maintenance procedures are recommended for health care facilities.

A1.1 Operating Rooms

a. Each operating room should be tested for positive pressure semi-annually or on an effective preventative maintenance schedule.

b. When HEPA filters are present within the diffuser of operating rooms, the filter should be replaced based on pressure drop.

c. Operating and caesarean delivery room ventilation systems shall operate at all times, except during maintenance and conditions requiring shutdown by the building's fire alarm system.

A1.2 Protective Environment (PE) Rooms. PE rooms should remain under positive pressure with respect to all adjoining rooms whenever an immunocompromised patient is present. PE rooms should be tested for positive pressure daily when an immunocompromised patient is present. When HEPA filters are present within the diffuser of protective environment rooms, the filter should be replaced based on pressure drop.

A1.3 Airborne Infection Isolation (AII) Rooms. AII rooms should remain under negative pressure relative to all adjoining rooms whenever an infectious patient is present. They should be tested for negative pressure daily whenever an infectious patient is present.

A1.4 Filters. Final filters and filter frames should be visually inspected for pressure drop and for bypass monthly. Filters should be replaced based on pressure drop with filters that provide the efficiencies specified in Table 6.4.

A2. SPECIAL MAINTENANCE FOR HVAC UNITS

The following special maintenance procedures are recommended for health care facilities.

A2.1 Fan-Coil Unit and Heat Pumps. The fan-coil unit and heat-pump filters serving patient rooms should be inspected monthly or on an effective preventative maintenance cycle for pressure drop and replaced when that pressure drop causes a reduction in airflow. Fan-coil unit and heat-pump drain pans under cooling coils should be cleaned monthly or on an effective preventative maintenance cycle.

A2.2 Fin-Tube Radiation Units, Induction Units and Convection Units. Fin-tube radiation units, induction units, and convection units serving patient rooms should be cleaned quarterly or on an effective preventative maintenance cycle.

A2.3 Fan-Powered Terminal Units. Fan-powered terminal-unit filters serving patient rooms should be inspected monthly or on an effective preventative maintenance cycle for pressure drop and replaced when the pressure drop causes a reduction in airflow.

A3. AIR INTAKE OPENING FOR AREAWAY

Figure A-3 illustrates the provisions of Section 6.3.1.4 for air intake openings for areaways.

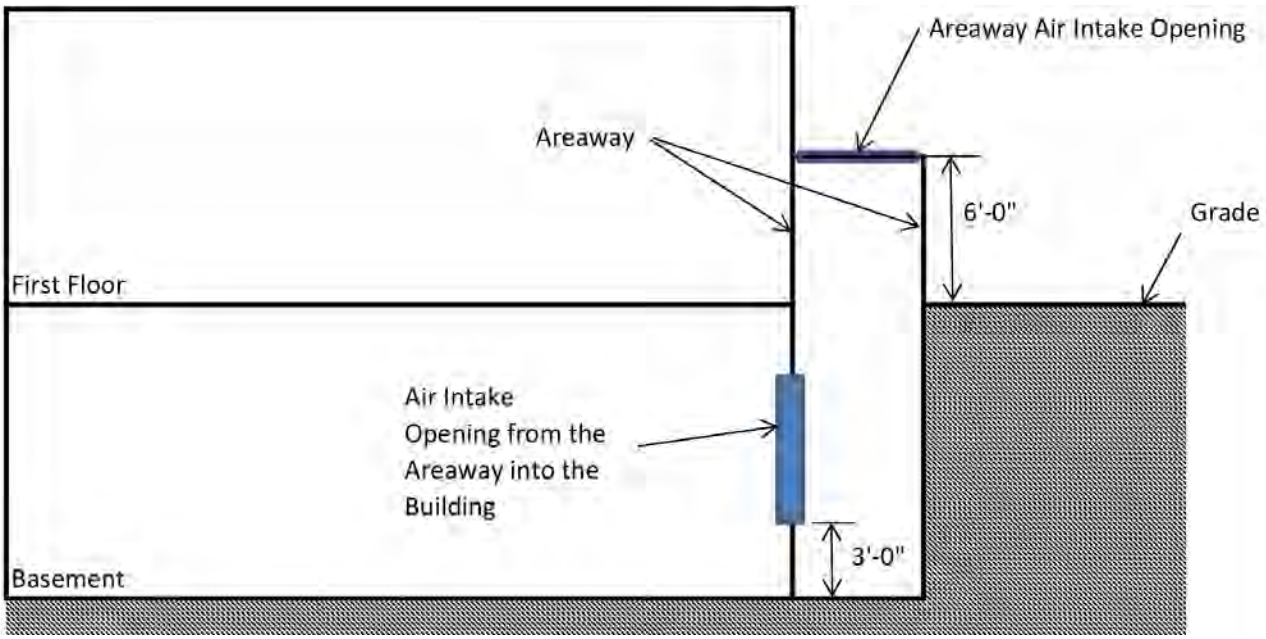

Figure A-3 Provisions for areaways.

(This appendix is not part of this standard. It is merely informative and does not contain requirements necessary for conformance to the standard. It has not been processed according to the ANSI requirements for a standard and may contain material that has not been subject to public review or a consensus process. Unresolved objectors on informative material are not offered the right to appeal at ASHRAE or ANSI.)

INFORMATIVE APPENDIX B
INFORMATIVE REFERENCES AND BIBLIOGRAPHY

ACS. 2000. *Guidelines for Optimal Ambulatory Surgical Care and Office-based Surgery*, Third ed. American College of Surgeons, Chicago, IL.

ASHRAE. 2005b. *Minimizing Indoor Mold Problems through Management of Moisture in Building Systems*. ASHRAE Position Document. ASHRAE, Atlanta.

ASHRAE. 2009. ASHRAE Handbook—*Fundamentals*, Chapter 20, "Space Air Diffusion." Atlanta: ASHRAE.

ASHRAE. 2010a. ANSI/ASHRAE Standard 55, *Thermal Environmental Conditions for Human Occupancy.* Atlanta: ASHRAE.

ASHRAE. 2010b. ANSI/ASHRAE Standard 62.1, *Ventilation for Acceptable Indoor Air Quality.* Atlanta: ASHRAE.

ASHRAE. 2011. *ASHRAE Handbook—Applications*, Chapter 8, "Health Care Facilities." Atlanta: ASHRAE.

ASHRAE. 2012. ANSI/ASHRAE Standard 52.2, *Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size.* Atlanta: ASHRAE.

ASHRAE. 2013. *HVAC Design Manual for Hospitals and Clinics*, 2nd Edition. Atlanta: ASHRAE.

CDC. 2005. *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities*. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA.

CDC. 2003. *Guidelines for Environmental infection control in health-care facilities*. Morbidity and Mortality Weekly Report (MMWR). U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Atlanta, GA.

Coogan, J.J. 1996. Effects of surrounding spaces on rooms pressurized by differential flow control. *ASHRAE Transactions* 102(1).

CSA Group. 2010. CAN/CSA-Z317.2-01, *Special Requirements for Heating, Ventilation, and Air Conditioning Systems in Health Care Facilities.* Toronto: CSA Group.

FGI. 2010. *Guidelines for Design and Construction of Health Care Facilities.* Facility Guidelines Institute, American Society for Healthcare Engineering, Chicago, IL

Hayden, C.S., II, O.E. Johnston, R.T. Hughes, and P.A. Jensen. 1998. Air volume migration from negative pressure isolation rooms during entry/exit. *Applied Occupational and Environmental Hygiene* 13(7):518–527.

Hermans, RD. 2000. Health care facility design manual-room design. *ASHRAE Transactions* 106(2).

IEST. 2005. IEST PR-CC001.3, *HEPA and ULPA Filters*. Arlington Heights, IL: Institute of Environmental Sciences and Technology.

Lewis, J.R, 1987. Operating room air distribution effectiveness. *ASHRAE Transactions* 93(2):1191–98.

Memarzadeh, F. 2013. Literature review: Room Ventilation and Airborne Disease Transmission. Nomograph, American Society for Healthcare Engineering, Chicago, IL.

Memarzadeh, F., and A. Manning. 2002. Comparison of operating room ventilation systems in the protection of the surgical site. *ASHRAE Transactions* 108(2)

Memarzadeh, F. and Z. Jiang. 2004. *Effects of Operating Room Geometry and Ventilation System Parameter Variations on the Protection of the Surgical Site*. IAQ 2004: Critical Operations: Supporting the Healing Environment through IAQ Performance Standards.

NFPA. 2012. NFPA-99, *Standard for Health Care Facilities*. Quincy, MA: National Fire Protection Association.

Ninomura, P., and J. Bartley. 2001. New ventilation guidelines for health-care facilities. *ASHRAE Journal*, June 2001, Atlanta, GA.

Ninomura, P., J. Bartley, and C. Rousseau. 2011. Health care standard update. *ASHRAE Journal* (March 2011):56–60.

OSHA. 29 CFR Part 1910.1047, *Occupational Exposure to Ethylene Oxide*. U.S. Department of Labor, Occupational Safety and Health Administration, Washington, D.C.

SMACNA. 2000. *Duct Cleanliness for New Construction Guidelines*. Chantilly, VA: Sheet Metal And Air Conditioning Contractors' National Association, Inc.

USP. 2008. National Formulary, USP-797, Pharmaceutical Compounding—Sterile Preparations. U.S. Pharmacopeial Convention, Rockville, MD.

(This appendix is not part of this standard. It is merely informative and does not contain requirements necessary for conformance to the standard. It has not been processed according to the ANSI requirements for a standard and may contain material that has not been subject to public review or a consensus process. Unresolved objectors on informative material are not offered the right to appeal at ASHRAE or ANSI.)

INFORMATIVE APPENDIX C
ADDENDA DESCRIPTION INFORMATION

ANSI/ASHRAE/ASHE Standard 170-2013 incorporates ANSI/ASHRAE/ASHE Standard 170-2008 and Addenda a, b, d, e, f, g, h, j, k, l, m, n, p, q, r, s, t, u, v, w, x, y, z, ab, and ac to ANSI/ASHRAE/ASHE Standard 170-2008. Table C-1 lists each addendum and describes the way in which the standard is affected by the change. It also lists the ASHRAE, ASHE and ANSI approval dates for each addendum.

TABLE C-1 Addenda to ANSI/ASHRAE/ASHE Standard 170-2008

Addendum	Section(s) Affected	Description of Changes*	Approval Dates: • Standards Committee • ASHRAE Board • ASHE Board • ANSI
a	Table 7-1 (renumbered as Table 7.1)	The changes in this addendum clear up inconsistencies regarding design parameters for spaces. The following discusses the specific changes implemented in this addendum. 1. Modifications to Table 7-1, "Design Parameters for Newborn Intensive Care." This change modifies the table entry for "Newborn intensive care" under the "Design Temperature" column to be the same as the table entry for "Newborn nursery suite." 2. Modifications to Table 7-1, "Design Parameters for Corridor." This change modifies the Table entry for "Corridor" under the "Function of Space" column. 3. Modifications to Table 7-1 note (k). This change modifies the note to denote that some entries have only a maximum relative humidity requirement. This change also deletes the word "control" and its associated interpretations from the text and replaces it with new text. 4. Modifications to Table 7-1 note (n). This change modifies the note to denote which type of "monitoring device alarms" is the subject of the sentence, since the note discusses a variety of topics.	June 20, 2009 June 24, 2009 June 2, 2009 July 25, 2009
b	Table 6-1 (renumbered as Table 6.4); Section 6.3.1; New Section 6.4.3; Sections 7.4.1 and 7.5.1; Table 7-1 (renumbered as Table 7.1); Informative Appendix B	This addendum adds additional requirements and clarifies some previous requirements. Coordination with both ASHRAE Standard 62.1 and the *Guidelines for Design and Construction of Health Care Facilities* are reflected in this addendum. Specifically, it implements the following changes: 1. Modifications to Table 6-1 and footnotes (c) and (d): The HEPA filter utilized by the table is more accurately defined. 2. Modifications to Section 6.3.1, "Outdoor Air Intakes": relief air discharges are exempted from the requirements for outdoor intakes. 3. Modifications to Section 6.4, "Filtration": Requirements to improve the performance of filter banks are added to address the problem of air bypassing the filter media. 4. Modifications to Section 7.4, "Surgery Rooms": Specific requirements for temperature control to operating rooms are added. 5. Modifications to Section 7.5.1, "Morgue and Autopsy Rooms": Requirements are added for a minimum differential pressure from these spaces that may contain potentially infectious remains. 6. Modifications to Table 7-1: A new entry for "Intermediate care" is added and the entries for "Triage" and "Radiology waiting rooms" are revised. The "RH" column header for all entries is revised. Twelve different laboratory entries in the "Air Recirculated by Means of Room Units" column are revised to permit recirculating room units to be used within these spaces.	October 14, 2009 October 24, 2009 September 24, 2009 November 16, 2009
d	Table 7-1 (renumbered as Table 7.1)	Based upon the findings of recent research, this addendum reduces the lower limit of the design humidity range for eight space types listed in Standard 170. All of these spaces are designed for short-term patient treatment stays. For these select spaces, this addendum reduces the lower design humidity limit from 30% to 20% rh.	June 26, 2010 June 30, 2010 July 9, 2010 July 10, 2010

* These descriptions may not be complete and are provided for information only.

TABLE C-1 Addenda to ANSI/ASHRAE/ASHE Standard 170-2008 *(Continued)*

Addendum	Section(s) Affected	Description of Changes*	Approval Dates: • Standards Committee • ASHRAE Board • ASHE Board • ANSI
e	Sections 7.2.1, 6.3.2, and 10	This addendum deletes references to MERV 17 to be consistent with previously published Addendum b, clarifies the meaning of "occupied space" regarding the requirements of certain exhaust ductwork systems, and adds an additional reference to Section 9, "Normative References."	January 29, 2011 February 2, 2011 January 28, 2011 February 3, 2011
f	Sections 7.2.1 and 7.2.2; New Section 7.2.3; Table 7-1 (renumbered as Table 7.1)	This addendum makes several miscellaneous changes to the current standard: (1) It clarifies the requirements for an AII room regarding a potential anteroom and the potential use of the AII room for patients other than those the room was designed for; (2) it clarifies the requirements for a PE room regarding a potential anteroom; and (3) it adds design requirements for a combination AII/PE space that has been previously defined by the FGI Guidelines.	January 29, 2011 February 2, 2011 January 28, 2011 February 3, 2011
g	Sections 3 and 9; Table 7-1 (renumbered as Table 7.1)	This addendum revises the requirements concerning the application of different types of ventilation diffusers in certain spaces.	January 29, 2011 February 2, 2011 January 28, 2011 March 3, 2011
h	Sections 6.4, 6.5.3, and 7.1	This proposed addendum clarifies the use of recirculating HVAC units through modifications to four parts of the current standard.	June 25, 2011 June 29, 2011 May 16, 2011 July 27, 2011
j	Section 3; Table 6-1 (renumbered as Table 6.4); Table 7-1 (renumbered as Table 7.1)	This addendum adds filtration requirements for certain types of residential health care facilities.	October 2, 2012 October 26, 2012 September 22, 2012 October 27, 2012
k	New Section 6.8	This addendum clarifies the requirement that "all" room air be exhausted directly to the outdoors and provides limitations as to the reuse of exhaust air for energy recovery.	January 26, 2013 January 29, 2013 January 18, 2013 January 30, 2013
l	Section 7.4.1; Table 7-1 (renumbered as Table 7.1)	This addendum makes the airflow requirements of Section 7.4.1 apply to both Caesarian delivery rooms and operating/surgical cystoscopic rooms. Both of these spaces are typically already programmed as Class B surgeries. This addendum also provides additional entries for Table 7-1.	January 21, 2012 January 25, 2012 December 9, 2011 January 26, 2012
m	Section 6.7.1	This addendum clarifies the requirements in Section 6.7.1 for the use of fully ducted return systems by recognizing that some spaces requiring a negative pressure relationship with the adjacent space require a fully ducted exhaust system rather than a return air system. This addendum also adds four spaces to meet the requirement for being fully ducted.	January 21, 2012 January 25, 2012 December 9, 2011 January 26, 2012
n	Section 7.1; Section 9	This addendum clarifies requirements for the calculation of outdoor air quantities for air-handling systems. This addendum provides designers with two alternative calculation pathways. The Project Committee considers that these multiple methods afford flexibility to a designer as appropriate to the varying system sizes and objectives that are involved in the outdoor air calculation process. As this standard provides specific guidance on the type of supply air outlets that shall be utilized in the varied healthcare environments, as indicated in Table 6-2 (renumbered as Table 6.7.2), the committee has determined that the minimum outdoor air change rates indicated in Table 7-1 represent the zone outdoor airflow, (thus defining the zone air distribution effectiveness for these spaces at 1.0 and factored into the determination of these total and outdoor air change rates) as may be needed for use in calculations defined by this addendum and including the Ventilation Rate Procedure of ASHRAE Standard 62.1.	January 26, 2013 January 29, 2013 January 18, 2013 January 30, 2013

* These descriptions may not be complete and are provided for information only.

TABLE C-1 Addenda to ANSI/ASHRAE/ASHE Standard 170-2008 *(Continued)*

Addendum	Section(s) Affected	Description of Changes*	Approval Dates: • Standards Committee • ASHRAE Board • ASHE Board • ANSI
p	Table 7-1 (renumbered as Table 7.1)	This addendum adds entries to Table 7-1. A "Nourishment area or room" is defined by FGI-2010 2.1-2.6.7. A nourishment area that is not enclosed by a door is typically adjacent to a patient corridor and is treated similarly in Table 7-1.	October 2, 2012 October 26, 2012 July 26, 2012 October 27, 2012
q	Sections 6.3.1 and 6.5.3	This addendum provides additional information to the designer concerning other potential pharmacy requirements that may be imposed by State pharmacy regulations. The addendum also provides clarification concerning a configuration of air intake not explicitly described previously. This addendum also addresses radiant heating systems utilizing wall panels.	October 2, 2012 October 26, 2012 September 22, 2012 October 27, 2012
r	Sections 3, 5, and 6.1.2; New Sections 6.4.4 and 6.5.4; Sections 6.6 and 8.2; Table 6-1 (renumbered as Table 6.4); New Sections 6.7.3, 6.7.4, 6.7.5 and 6.8; Sections 7.1, 7.4.1 and 7.5.2; Table 7-1 (renumbered as Table 7.1) notes; Sections 8.2 and A1.1; Informative Appendix B	The changes included in the addendum are primarily intended to coordinate with the 2010 *Guidelines for the Design and Construction of Health Care Facilities*. The following discusses the specific changes: 1. Two additional definitions are added to provide supplemental guidance regarding the meaning of "absorption distance" and "essential accessories." 2. Change to Section 5 is added to clarify that "equipment" in this section refers to non-HVAC equipment. 3. Change to Section 6.1.2 is added to coordinate and clarify terminology pertaining to boiler capacity and operation. 4. The specific exception for cooling is not required, since it would just be another component of the owner's facility operation plan. This change to Section 6.1.2.2 deletes the exception. 5. New Section 6.4.4 is added to minimize air leakage around and between filters. 6. Change to Table 6-1 is added to not require a second filter bank for psychiatric facilities. 7. Relocate design requirements for cooling towers from Section 8.2d to a new Section 6.5.4. 8. Change to Section 6.6 is added to minimize moisture impingement on ductwork. 9. New Section 6.7.3 is added to require coordination between smoke zones and air-handling-unit zones to minimize the number of smoke dampers required in a facility. 10. New Section 6.7.4 is added to improve maintainability of fire and smoke dampers over the life of a facility. 11. New Section 6.7.5 is added to prevent ductwork from impairing (or being impaired by) special wall construction. 12. New Section 6.8 is added to minimize the ability of patients to tamper with HVAC equipment. 13. Editorial changes to Section 7.1 are made to remove incorrect note reference and redundant requirements. 14. Exception to Section 7.4.1 is added to allow improved particulate control in operating rooms, as indicated by NIH research. 15. New Section 7.5.2 is added to improve infection control in spaces where infected patients are likely to be coughing. 16. Relocate text from note (n) of Table 7-1 to note (a). 17. Delete example from note (j) of Table 7-1. 18. Remove redundant text in Section 8.2. 19. Clarify intended operation of operating and caesarean delivery rooms in Section A1.1.	June 23, 2012 June 27, 2012 June 29, 2012 June 29, 2012
s	Section s 6.1.2, 6.6 and 6.7.4; New Section 7.6; Table 7-1 (renumbered as Table 7.1) notes	These changes are intended to clarify and coordinate requirements of the standard with the FGI *Guidelines for Design and Construction of Health Care Facilities*.	June 23, 2012 June 27, 2012 June 29, 2012 June 29, 2012
t	Foreword; Section 6.1.2.1; Informative Appendix B	This addendum updates references to the *Guidelines for Design and Construction of Health Care Facilities*.	October 2, 2012 October 26, 2012 September 22, 2012 October 27, 2012
u	Table 7-1 (renumbered as Table 7.1)	This addendum clarifies note (w) to Table 7-1, "Design Parameters."	June 22, 2013 June 26, 2013 July 3, 2013 July 4, 2013

* These descriptions may not be complete and are provided for information only.

TABLE C-1 Addenda to ANSI/ASHRAE/ASHE Standard 170-2008 *(Continued)*

Addendum	Section(s) Affected	Description of Changes*	Approval Dates: • Standards Committee • ASHRAE Board • ASHE Board • ANSI
v	Table 7-1 (renumbered as Table 7.1)	This addendum provides clarification concerning design relative humidity requirements for spaces whose function is recovery. Addendum d noted that, based on recent research, a reduction in the lower limit of the design humidity range for eight spaces designed for short-term patient stays was warranted. Addendum v recognizes the applicability of that research to the clinical use of spaces whose function is recovery that are also designed for short-term patient stays. This change reduces the lower design humidity limit from 30% to 20% rh to match that of those spaces noted in Addendum d.	January 26, 2013 January 29, 2013 January 18, 2013 January 30, 2013
w	Table 7-1 (renumbered as Table 7.1)	This addendum clarifies Table 7-1, "Design Parameters," minimum requirements for gastrointestinal endoscopy procedure rooms. The design relative humidity for this short-term-stay space has been lowered similar to that which occurred for Addendum d (Surgeries) and Addendum v (Recovery room). This addendum provides clarification concerning design relative humidity requirements for spaces which function to perform gastrointestinal endoscopy procedures and reduces the lower design humidity limit from 30% to 20% rh. This addendum provides clarification concerning the pressure relationship to adjacent area requirements for spaces in which gastrointestinal endoscopy procedures are performed. The pressurization requirement has been revised to "No Requirement" such that gastrointestinal endoscopy procedures may occur within positive pressure rooms, negative pressure rooms, or rooms with no controlled pressure.	June 22, 2013 June 26, 2013 July 3, 2013 July 4, 2013
x	Table 6-1 (renumbered as Table 6.4)	This addendum adds filtration requirements in Table 6-1, "Minimum Filter Efficiencies," for inpatient hospice and assisted living facilities. This addendum also adds design parameters in Table 7-1, "Design Parameters," for resident unit corridors.	June 22, 2013 June 26, 2013 July 3, 2013 July 24, 2013
y	New Section 6.9	This addendum adds restrictions on the use of duct lining. These requirements are similar to those of the 2010 FGI *Guidelines for the Design and Construction of Health Care Facilities* but have been clarified.	September 26, 2013 November 8, 2013 September 16, 2013 December 5, 2013
z	Table 7-1 (renumbered as Table 7.1)	This addendum clarifies requirements for an emergency department examination/treatment room in Table 7-1, "Design Parameters." The function of the emergency department examination/treatment room is described in FGI-2010 paragraph 2.2-3.1.3.6.	June 22, 2013 June 26, 2013 July 3, 2013 July 24, 2013
ab	Table 7-1 (renumbered as Table 7.1)	This addendum clarifies Table 7-1, "Design Parameters," minimum requirements for patient rooms. The "Patient room" table entry with note (s.) previously allowed four minimum total ach for this space with the use of supplemental heating and/or cooling systems. The patient-room requirements have been clarified such that four minimum total ach is the space requirement regardless of the use of supplemental heating and/or cooling systems. The last sentence of note (s) was not revised by this addenda; it was relocated to a new note (x) and reapplied to the same table entry for patient rooms.	June 22, 2013 June 26, 2013 July 3, 2013 July 24, 2013
ac	Section 6.7.1	This addendum adds requirements for ducted returns for inpatient facilities.	July 26, 2013 July 30, 2013 July 20, 2013 July 31, 2013

* These descriptions may not be complete and are provided for information only.

NOTICE

INSTRUCTIONS FOR SUBMITTING A PROPOSED CHANGE TO THIS STANDARD UNDER CONTINUOUS MAINTENANCE

This standard is maintained under continuous maintenance procedures by a Standing Standard Project Committee (SSPC) for which the Standards Committee has established a documented program for regular publication of addenda or revisions, including procedures for timely, documented, consensus action on requests for change to any part of the standard. SSPC consideration will be given to proposed changes within 13 months of receipt by the manager of standards (MOS).

Proposed changes must be submitted to the MOS in the latest published format available from the MOS. However, the MOS may accept proposed changes in an earlier published format if the MOS concludes that the differences are immaterial to the proposed change submittal. If the MOS concludes that a current form must be utilized, the proposer may be given up to 20 additional days to resubmit the proposed changes in the current format.

ELECTRONIC PREPARATION/SUBMISSION OF FORM FOR PROPOSING CHANGES

An electronic version of each change, which must comply with the instructions in the Notice and the Form, is the preferred form of submittal to ASHRAE Headquarters at the address shown below. The electronic format facilitates both paper-based and computer-based processing. Submittal in paper form is acceptable. The following instructions apply to change proposals submitted in electronic form.

Use the appropriate file format for your word processor and save the file in either a recent version of Microsoft Word (preferred) or another commonly used word-processing program. Please save each change proposal file with a different name (for example, “prop01.doc,” “prop02.doc,” etc.). If supplemental background documents to support changes submitted are included, it is preferred that they also be in electronic form as word-processed or scanned documents.

For files submitted attached to an e-mail, ASHRAE will accept an electronic signature (as a picture; *.tif, or *.wpg) on the change submittal form as equivalent to the signature required on the change submittal form to convey non-exclusive copyright.

Submit an e-mail containing the change proposal files to:
change.proposal@ashrae.org

Alternatively, mail paper versions to:
ASHRAE
Manager of Standards
1791 Tullie Circle, NE
Atlanta, GA 30329-2305

Or fax them to:
Attn: Manager of Standards
404-321-5478

The form and instructions for electronic submittal may be obtained from the Standards section of ASHRAE’s Home Page, www.ashrae.org, or by contacting a Standards Secretary via phone (404-636-8400), fax (404-321-5478), e-mail (standards.section@ashrae.org), or mail (1791 Tullie Circle, NE, Atlanta, GA 30329-2305).

FORM FOR SUBMITTAL OF PROPOSED CHANGE TO AN ASHRAE STANDARD UNDER CONTINUOUS MAINTENANCE

NOTE: Use a separate form for each comment. Submittals (Microsoft Word preferred) may be attached to e-mail (preferred), or submitted in paper by mail or fax to ASHRAE, Manager of Standards, 1791 Tullie Circle, NE, Atlanta, GA 30329-2305. E-mail: change.proposal@ashrae.org. Fax: +1-404/321-5478.

1. Submitter:

Affiliation:

Address: City: State: Zip: Country:

Telephone: Fax: E-Mail:

I hereby grant ASHRAE the non-exclusive royalty rights, including non-exclusive rights in copyright, in my proposals. I understand that I acquire no rights in publication of the standard in which my proposals in this or other analogous form is used. I hereby attest that I have the authority and am empowered to grant this copyright release.

Submitter's signature: _____ Date: _____

All electronic submittals must have the following statement completed:

I *(insert name)* _____, through this electronic signature, hereby grant ASHRAE the non-exclusive royalty rights, including non-exclusive rights in copyright, in my proposals. I understand that I acquire no rights in publication of the standard in which my proposals in this or other analogous form is used. I hereby attest that I have the authority and am empowered to grant this copyright release.

2. Number and year of standard:

3. Page number and clause (section), subclause, or paragraph number:

4. I propose to: *(check one)*

[ ] Change to read as follows
[ ] Add new text as follows
[ ] Delete and substitute as follows
[ ] Delete without substitution

Use underscores to show material to be added (<u>added</u>) and strike through material to be deleted (~~deleted~~). Use additional pages if needed.

5. Proposed change:

6. Reason and substantiation:

7. Will the proposed change increase the cost of engineering or construction? If yes, provide a brief explanation as to why the increase is justified.

[ ] Check if additional pages are attached. Number of additional pages: _____

[ ] Check if attachments or referenced materials cited in this proposal accompany this proposed change. Please verify that all attachments and references are relevant, current, and clearly labeled to avoid processing and review delays. *Please list your attachments here:*

POLICY STATEMENT DEFINING ASHRAE'S CONCERN FOR THE ENVIRONMENTAL IMPACT OF ITS ACTIVITIES

ASHRAE is concerned with the impact of its members' activities on both the indoor and outdoor environment. ASHRAE's members will strive to minimize any possible deleterious effect on the indoor and outdoor environment of the systems and components in their responsibility while maximizing the beneficial effects these systems provide, consistent with accepted standards and the practical state of the art.

ASHRAE's short-range goal is to ensure that the systems and components within its scope do not impact the indoor and outdoor environment to a greater extent than specified by the standards and guidelines as established by itself and other responsible bodies.

As an ongoing goal, ASHRAE will, through its Standards Committee and extensive technical committee structure, continue to generate up-to-date standards and guidelines where appropriate and adopt, recommend, and promote those new and revised standards developed by other responsible organizations.

Through its *Handbook*, appropriate chapters will contain up-to-date standards and design considerations as the material is systematically revised.

ASHRAE will take the lead with respect to dissemination of environmental information of its primary interest and will seek out and disseminate information from other responsible organizations that is pertinent, as guides to updating standards and guidelines.

The effects of the design and selection of equipment and systems will be considered within the scope of the system's intended use and expected misuse. The disposal of hazardous materials, if any, will also be considered.

ASHRAE's primary concern for environmental impact will be at the site where equipment within ASHRAE's scope operates. However, energy source selection and the possible environmental impact due to the energy source and energy transportation will be considered where possible. Recommendations concerning energy source selection should be made by its members.

ASHRAE · 1791 Tullie Circle NE · Atlanta, GA 30329 · www.ashrae.org

About ASHRAE

ASHRAE, founded in 1894, is an international building technology society with more than 50,000 members worldwide. The Society and its members focus on building systems, energy efficiency, indoor air quality, refrigeration, and sustainability. Through research, standards writing, publishing, certification and continuing education, ASHRAE shapes tomorrow's built environment today.

For more information or to become a member of ASHRAE, visit www.ashrae.org.

To stay current with this and other ASHRAE standards and guidelines, visit www.ashrae.org/standards.

Visit the ASHRAE Bookstore

ASHRAE offers its standards and guidelines in print, as immediately downloadable PDFs, on CD-ROM, and via ASHRAE Digital Collections, which provides online access with automatic updates as well as historical versions of publications. Selected standards are also offered in redline versions that indicate the changes made between the active standard and its previous version. For more information, visit the Standards and Guidelines section of the ASHRAE Bookstore at www.ashrae.org/bookstore.

IMPORTANT NOTICES ABOUT THIS STANDARD

To ensure that you have all of the approved addenda, errata, and interpretations for this standard, visit www.ashrae.org/standards to download them free of charge.

Addenda, errata, and interpretations for ASHRAE standards and guidelines are no longer distributed with copies of the standards and guidelines. ASHRAE provides these addenda, errata, and interpretations only in electronic form to promote more sustainable use of resources.

Product code: 86515 7/14
Errata noted in the list dated 2/27/14 have been corrected.